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10/702,344	11/06/2003	Douglas B. Gundel	58895US002	8102

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EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	
ART UNIT	**PAPER NUMBER**
1753	

NOTIFICATION DATE	DELIVERY MODE
05/17/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LegalUSDocketing@mmm.com
LegalDocketing@mmm.com

Office Action Summary	Application No.	Applicant(s)	
	10/702,344	GUNDEL, DOUGLAS B.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-20* is/are rejected.

7)☒ Claim(s) *4* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/23/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

DETAILED ACTION

Claim Rejections - 35 USC § 102

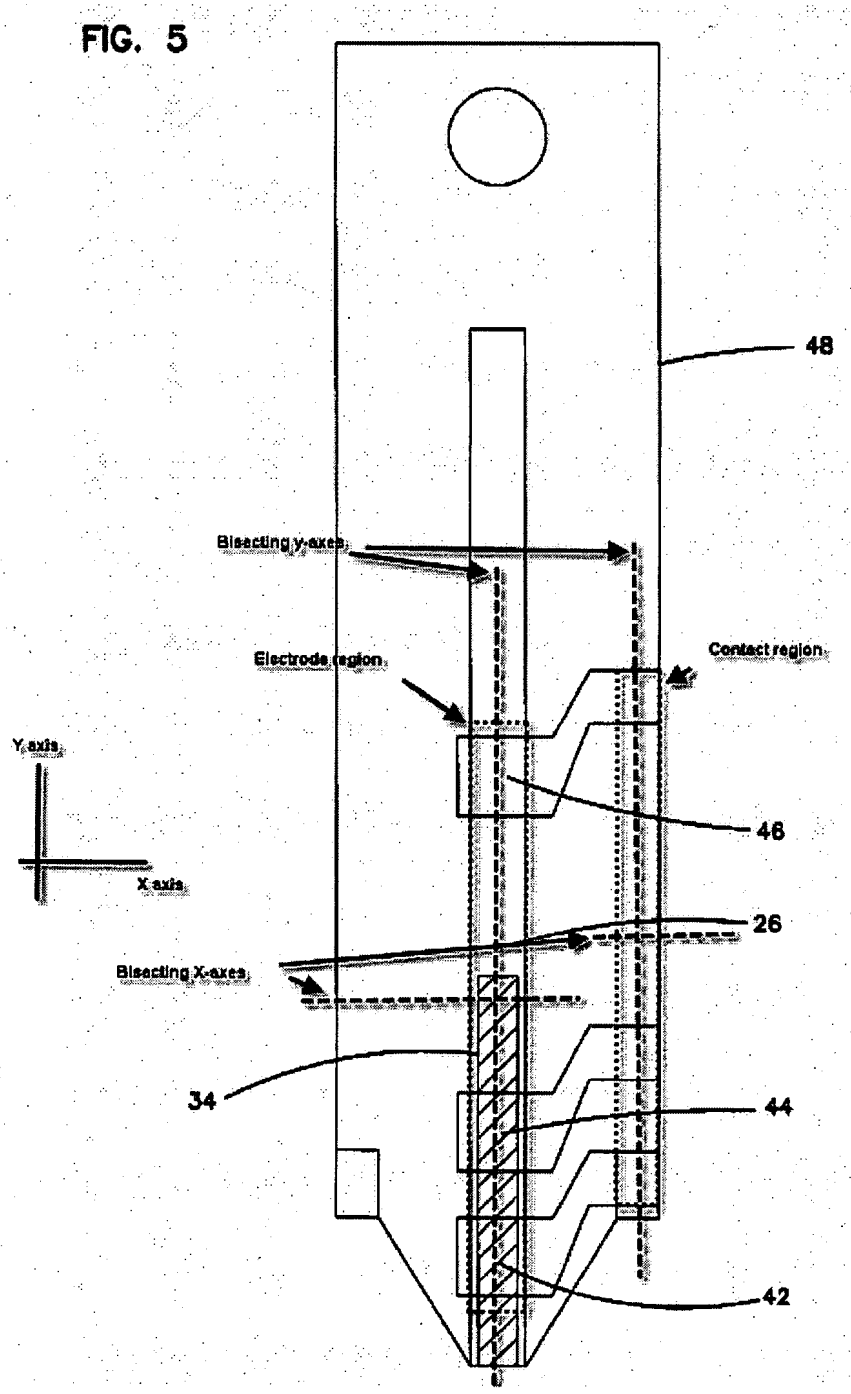
1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 5, and 19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Heller et al. (WO 98/35225 A1) ("Heller").

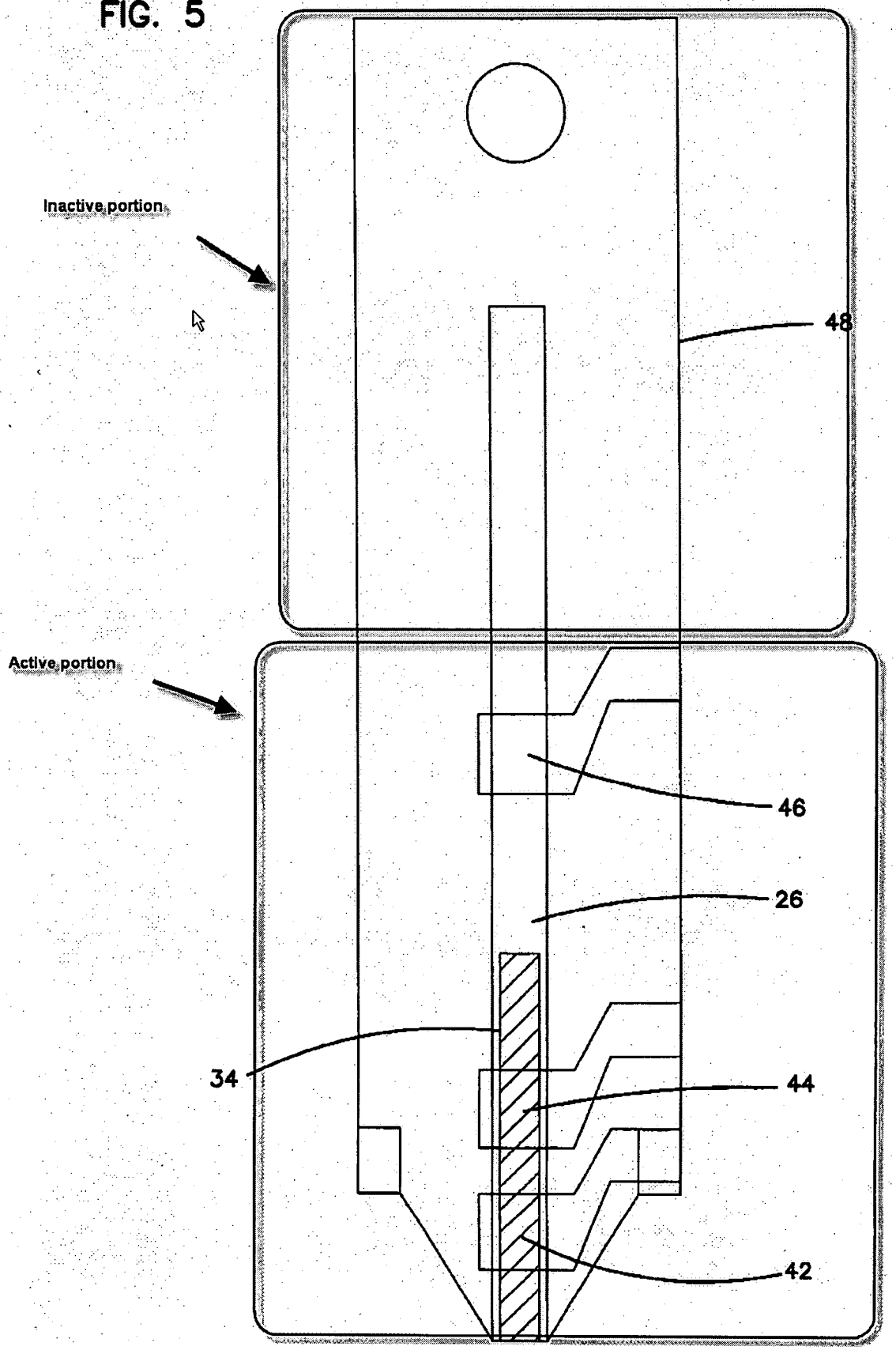
Addressing claim 1, Heller discloses an article comprising an electrochemical sensor strip (abstract) having circuits comprising electrodes in a region connected to contact pads in a contact region by conductive traces wherein the electrode region is off-set from the contact region in both an x direction parallel to the length of the sensor strip and a y direction parallel to the width of the sensor strip. See the labeled reproduction of Figure 5 below.

FIG. 5


48
Bisecting y-axes
Electrode region
Contact region
Y axis
X axis
46
26
Bisecting X-axes
34
44
42

Addressing claim 5, for the additional limitations of this claim see the labeled reproduction of Figure 5 below.

FIG. 5



Addressing claim 19, for the additional limitation of this claim see page 12, line 28 – page 13, line 01.

3. Claims 1, 2, 5, and 19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by McAleer et al. (US 5,708,247) ("McAleer").

Addressing claim 1, McAleer discloses an article comprising an electrochemical sensor strip (abstract) having circuits comprising electrodes in a region connected to contact pads in a contact region by conductive traces wherein the electrode region is off-set from the contact region in both an x direction parallel to the length of the sensor strip and a y direction parallel to the width of the sensor strip. See the labeled reproduction of Figure 1A below.

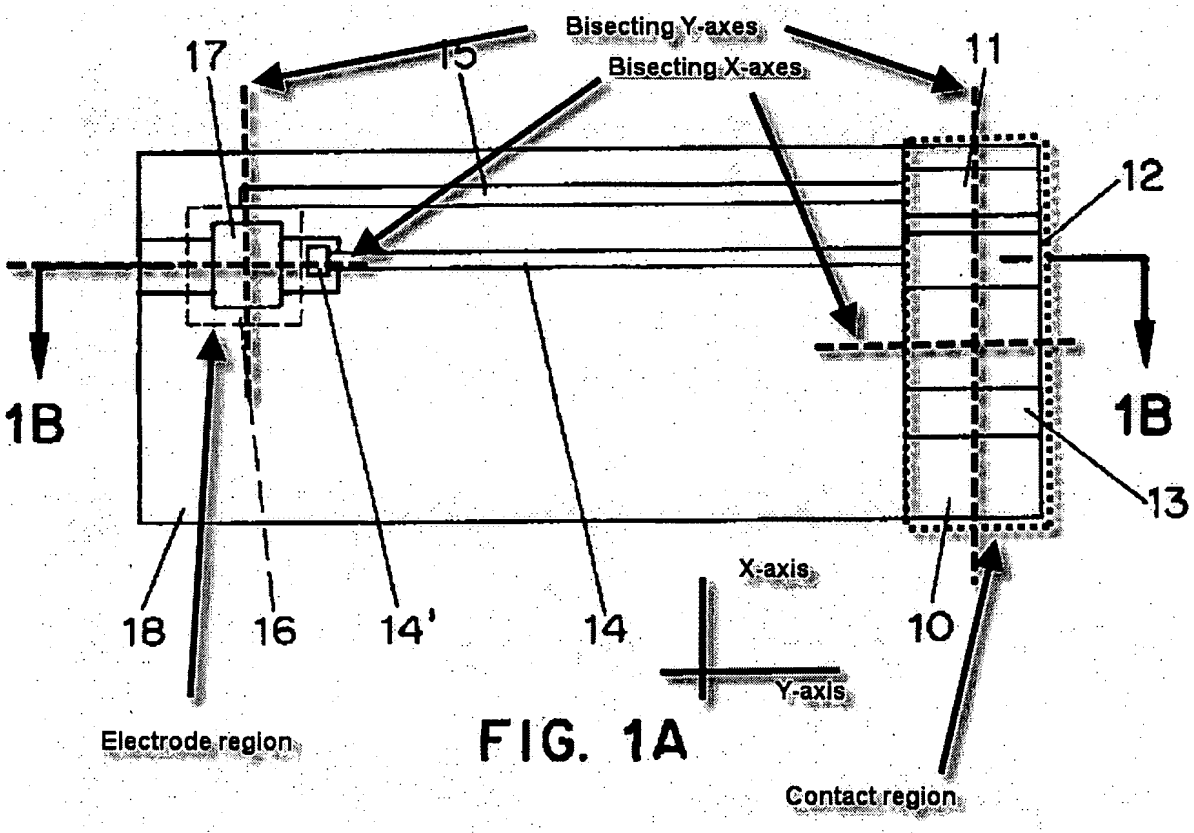


FIG. 1A

Addressing claim 2, as seen in Figure 1A contact pad 11, conductive trace 15, and conductive layer 16 together form a L-shaped circuit.

Addressing claim 5, for the additional limitations of this claim see the labeled reproduction of Figure 1A below.

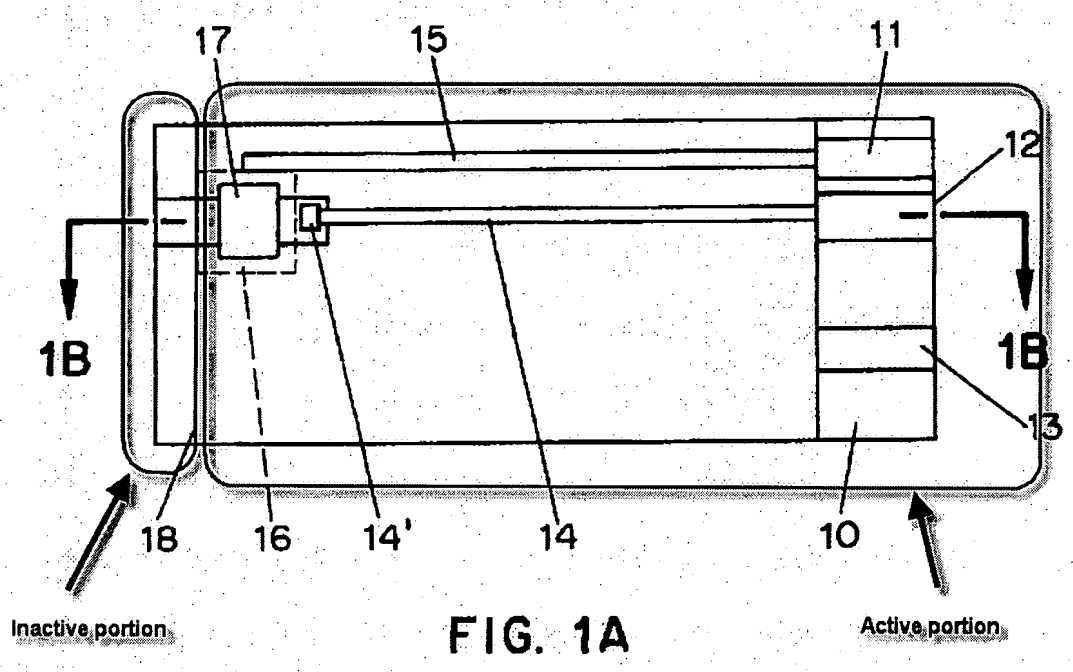


FIG. 1A

Addressing claim 19, for the additional limitation of this claim see col. 03:39-42.

4. Claims 1, 5, and 19 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Huang et al. (US 6,923,894 B2) ("Huang").

Huang discloses an article comprising an electrochemical sensor strip (abstract) having circuits comprising electrodes in a region connected to contact pads in a contact region by conductive traces wherein the electrode region is off-set from the contact region in both an x direction parallel to the length of the sensor strip and a y direction parallel to the width of the sensor strip. See the labeled reproduction of Figure 3 below.

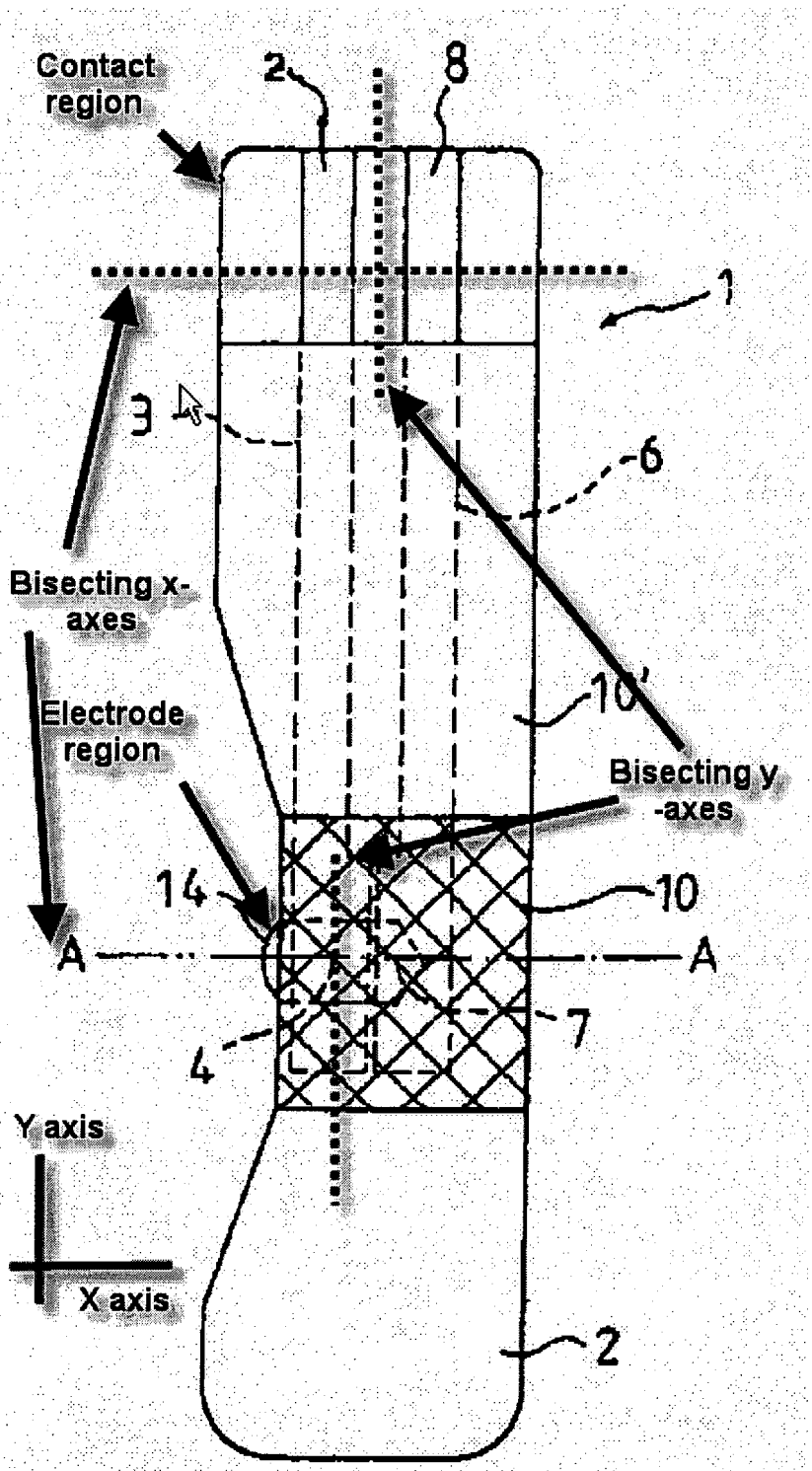

Contact region
2
8
1
3
6
Bisecting x-axes
Electrode region
10'
Bisecting y -axes
14
10
A
A
7
4
Y axis
X axis
2

FIG. 3

Addressing claim 5, for the additional limitations of this claim see the labeled reproduction of Figure 3 below.

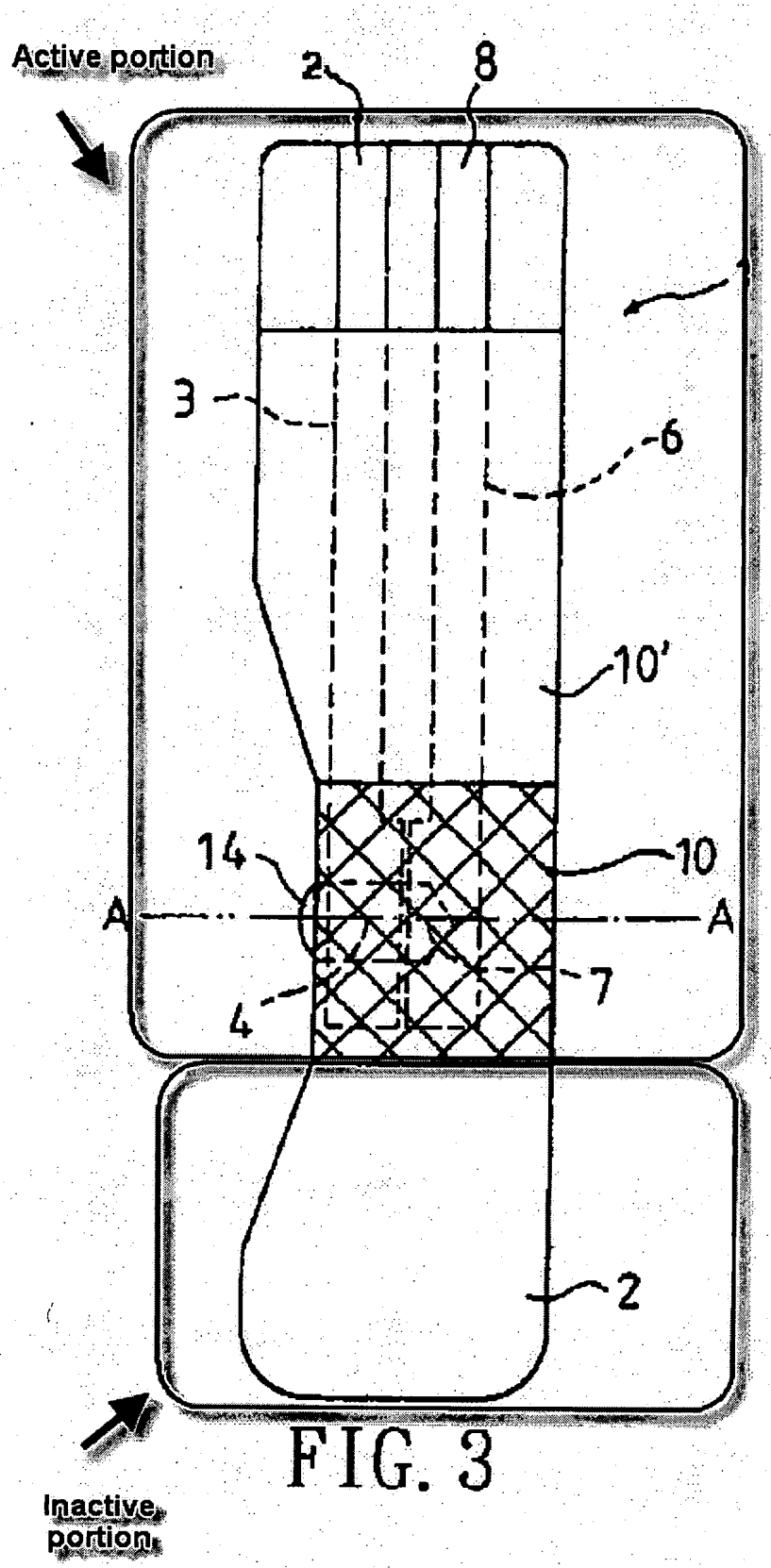


FIG. 3

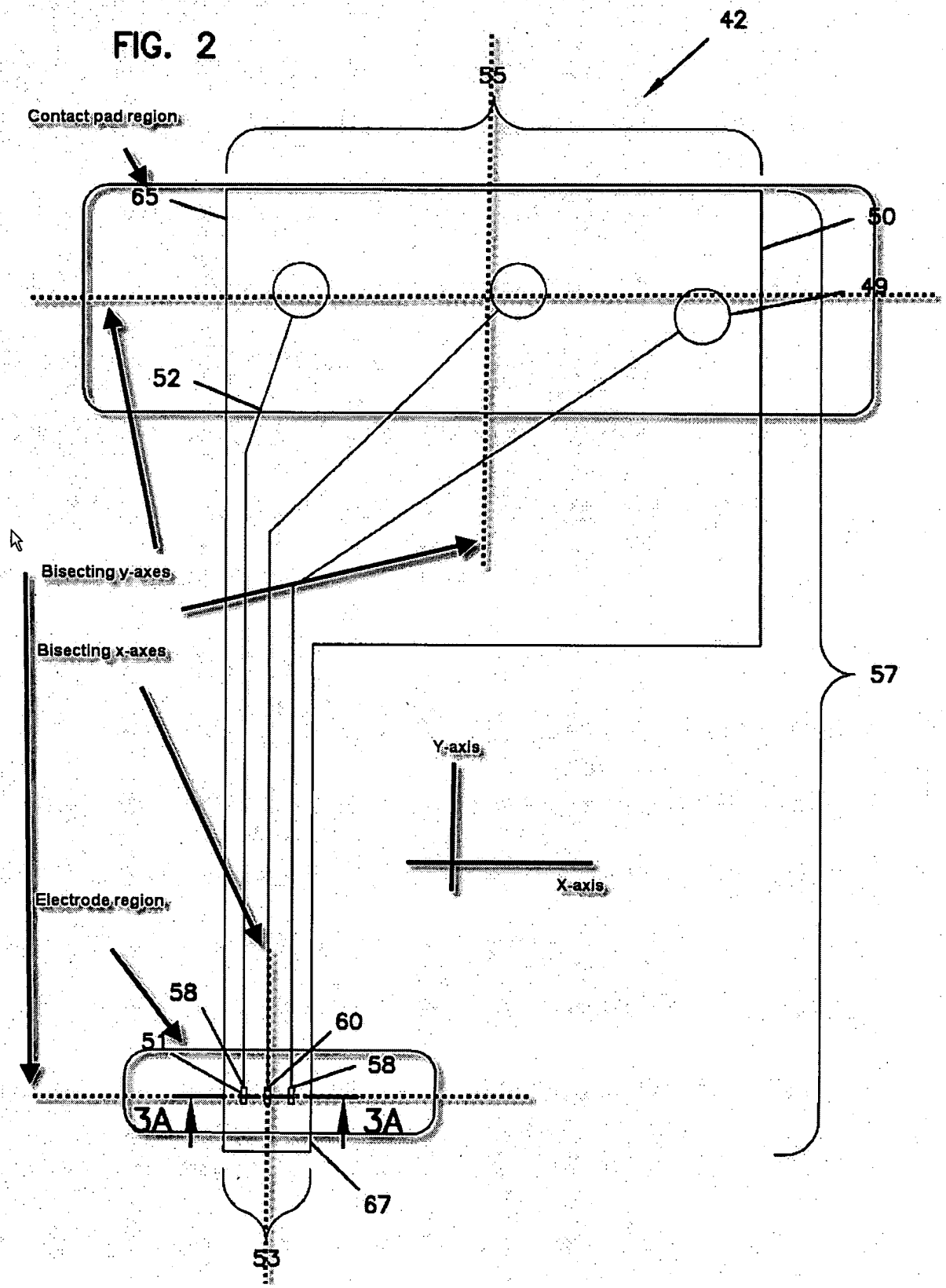
Addressing claim 19, for the additional limitation of this claim see col. 05:05-28.

5. Claims 1-3, 5, 10, 11, 19, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Nozoe et al. (US 5,741,634). According to the European examiner who prepared the International Search Report for International Application No. PCT/US2004/033948 Figure 3 and col. 01:22-40 and col. 04:62 – col. 05:27 teach the limitations of the rejected claims.

6. Claims 1 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Say et al. (US 6,175,752 B1).

For the limitations of claim 1 consider the labeled reproduction of Figure 2 below.

FIG. 2


42
55
Contact pad region
65
50
49
52
Bisecting y-axes
Bisecting x-axes
57
Y-axis
X-axis
Electrode region
58
60
51
58
3A
3A
67
53

For the addioal lioi of claim 19 see col. 01:01-20.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over McAleer et al. (US 5,708,247) ("McAleer") in view of Karinka et al. (US 6,939,450 B2) ("Karinka").

McAleer discloses an article comprising an electrochemical sensor strip (abstract) having circuits comprising electrodes in a region connected to contact pads in a contact region by conductive traces wherein the electrode region is off-set from the contact region in both an x direction parallel to the length of the sensor strip and a y direction parallel to the width of the sensor strip. See the labeled reproduction of Figure 1A below.

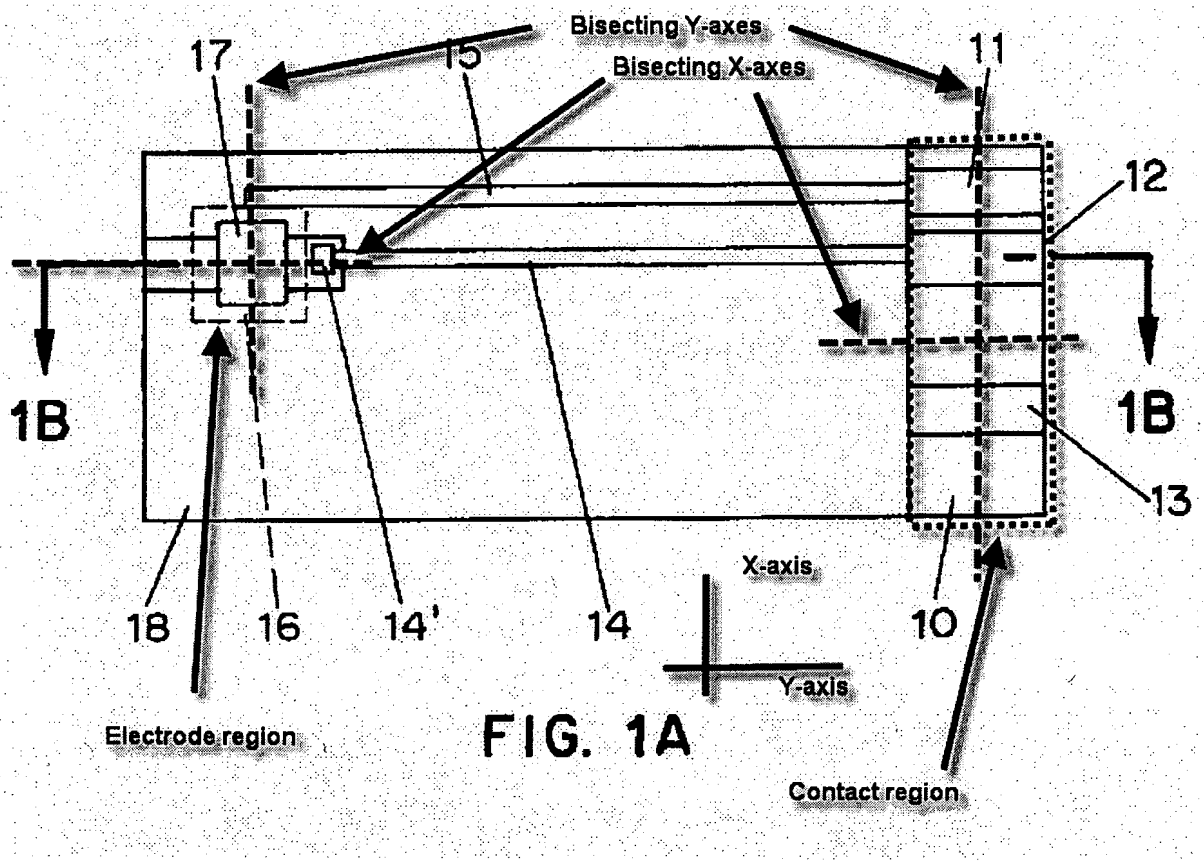


FIG. 1A

McAleer does not mention a trace having at least one 90° bend, although McAleer does disclose a third contact pad (13), presumably for a third electrode, laterally offset from the measurement region. See Figure 1A.

Karinka discloses an electrochemical test strip comprising a reference electrode (126), a working electrode (124), and a counter electrode (128). The reference electrode comprise a trace having at least one 90° bend. See the abstract and Figure 3.

It would have been obvious to one with ordinary skill in the art at the time of the invention to have the electrode at the end of the sample channel in McAleer be a counter electrode and to provide a separate reference electrode at the front of the sample channel, the reference electrode having a trace having at least one 90° bend, as taught by Karinka in the invention of McAleer because McAleer already provides an unused contact pad (13) laterally offset from the sample chamber and as taught by Karinka by providing a separate reference electrode form the counter electrode the accuracy of current measurements will be improved since the working electrode will better held at the desired potential than by using a dual counter/reference electrode. See in Karinka col. 07:09-50.

10. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over McAleer et al. (US 5,708,247) ("McAleer") in view of Bhullar et al. (US 6,488,828 B1) ("Bhullar").

McAleer discloses an article comprising an electrochemical sensor strip (abstract) having circuits comprising electrodes in a region connected to contact pads in a contact region by conductive traces wherein the electrode region is off-set from the contact region in both an x direction parallel to the length of the sensor strip and a y direction parallel to the width of the sensor strip. See the labeled reproduction of Figure 1A below.

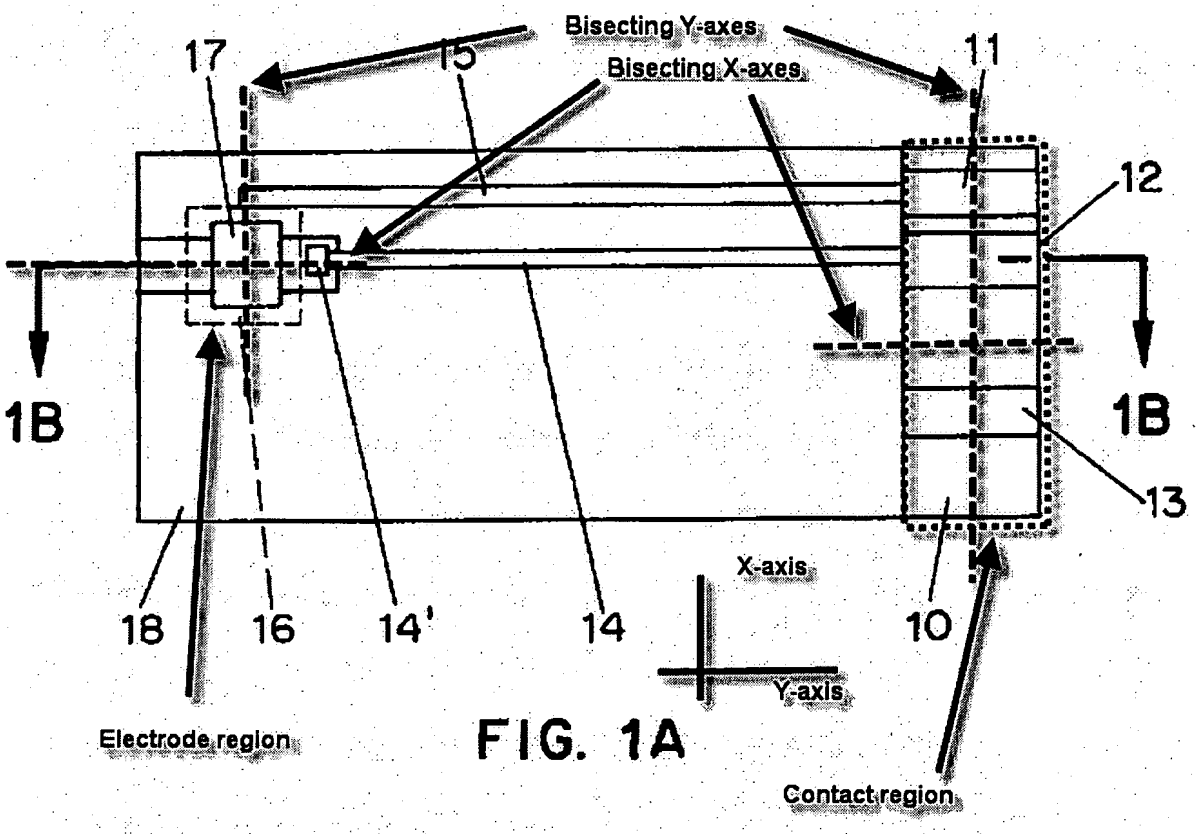


FIG. 1A

McAleer further discloses having the circuits located in an active portion and having the article further comprise an inactive portion. See the labeled reproduction of Figure 1A below.

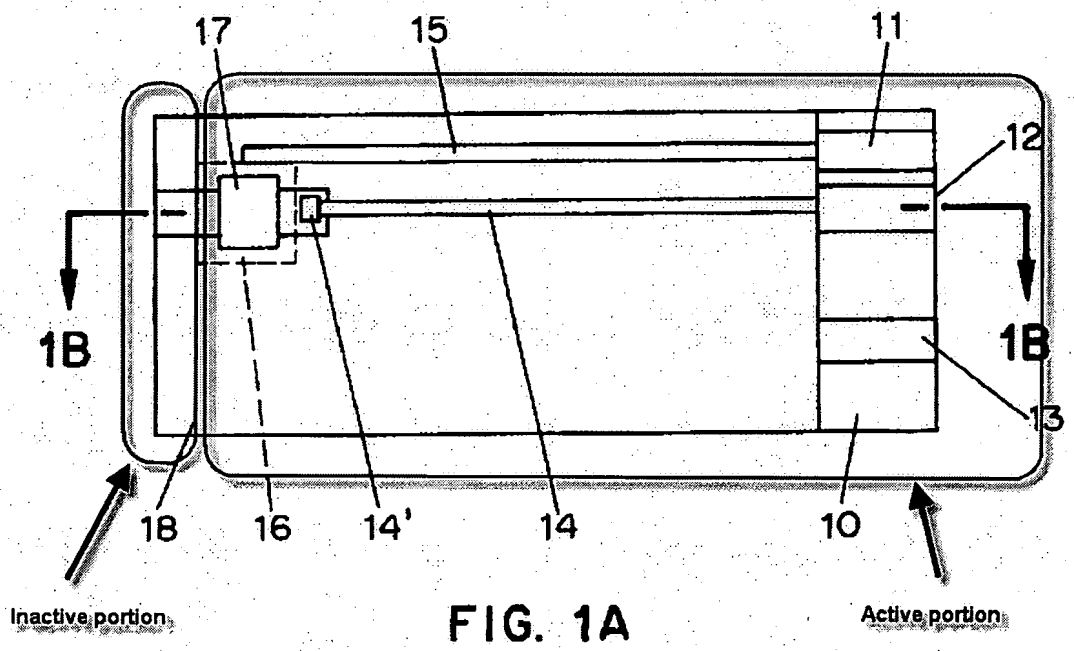


FIG. 1A

McAleer further does not disclose providing a handling tab in the inactive portion, particularly one that is bent at one or both ends.

Bhullar discloses an electrochemical biosensor test strip comprising a cover (24) on the top with a handling tab (48) at the front end of the biosensor, the handling tab being bent at one end. See the abstract and Figures 3 and 10.

It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a cover as taught by Bhullar in the invention of McAleer, which if similarly situated would locate the handling tab in the inactive portion of the biosensor of McAleer, because as taught by Bhullar then the biosensor "... can be closed after the initial opening to protect a sample site. Thus, the need to locate a storage container for eh biosensor either prior to se or before disposal is avoided. As such, providing biosensors with recloseable covers appreciably enhances the marketability and environmental friendliness of the biosensor." See col. 02:06-14.

11. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huang et al. (US 6,923,894 B2) ("Huang") in view of the CAPLUS abstract and Figure 2 of Moeller (DE 10020445 A1).

Huang discloses an article comprising an electrochemical sensor strip (abstract) having circuits comprising electrodes in an electrode region connected to contact pads in a contact region by conductive traces wherein the electrode region is off-set from the contact region in both an x direction parallel to the length of the sensor strip and a y

direction parallel to the width of the sensor strip. See the labeled reproduction of Figure 3 below.

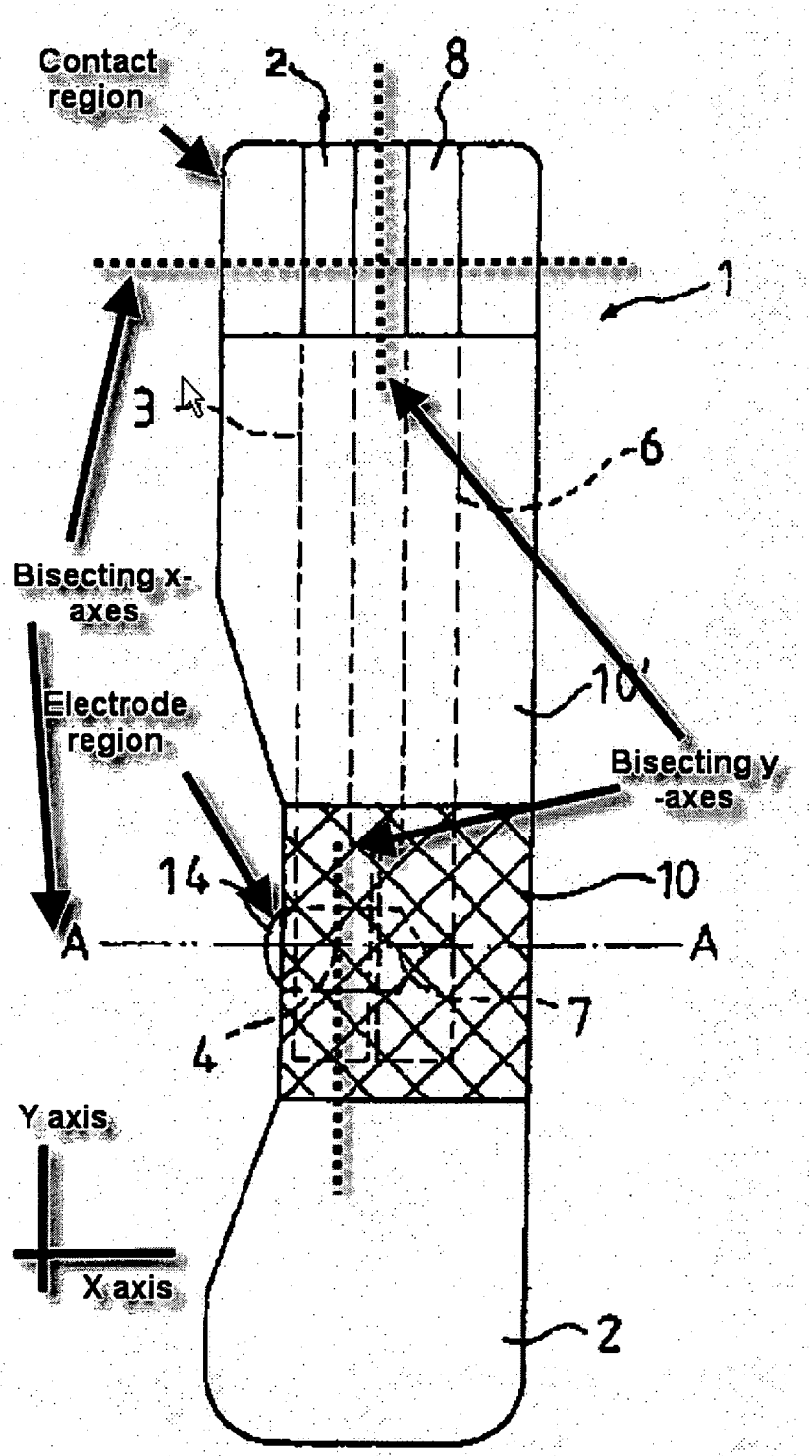

Contact region
2
8
1
3
6
Bisecting x-axes
Electrode region
10'
Bisecting y-axes
14
10
A
A
7
4
Y axis
X axis
2

FIG. 3

Huang further discloses having the circuits located in an active portion and having the article further comprise an inactive portion. See the labeled reproduction of Figure 3 below.

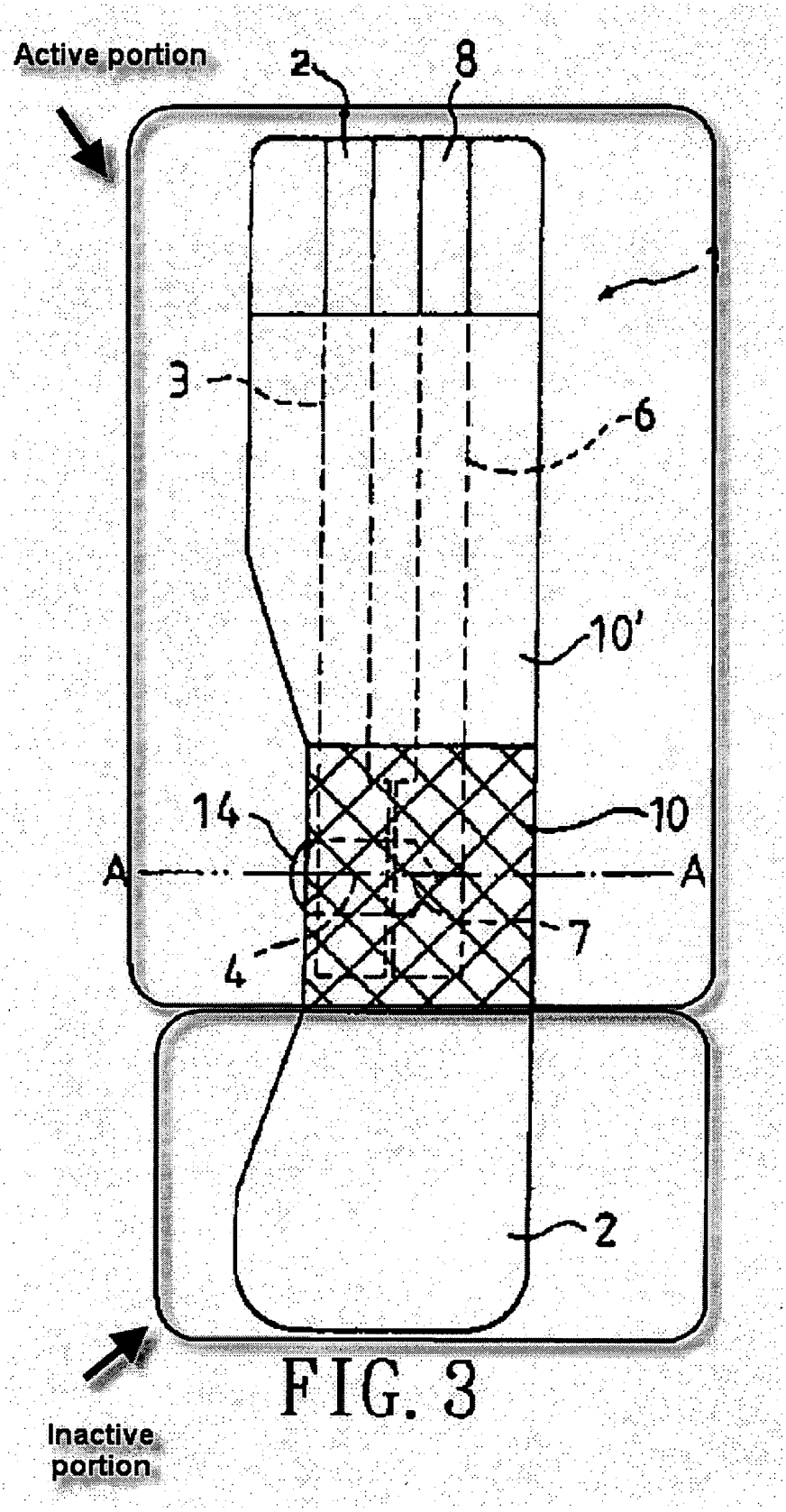


FIG. 3

Huang does not mention providing a handling tab in the inactive portion, particularly a handling tab that is textured.

Moeller discloses providing a handling tab that is connected to the upper side of a strip-type biosensor. See Figure 2.

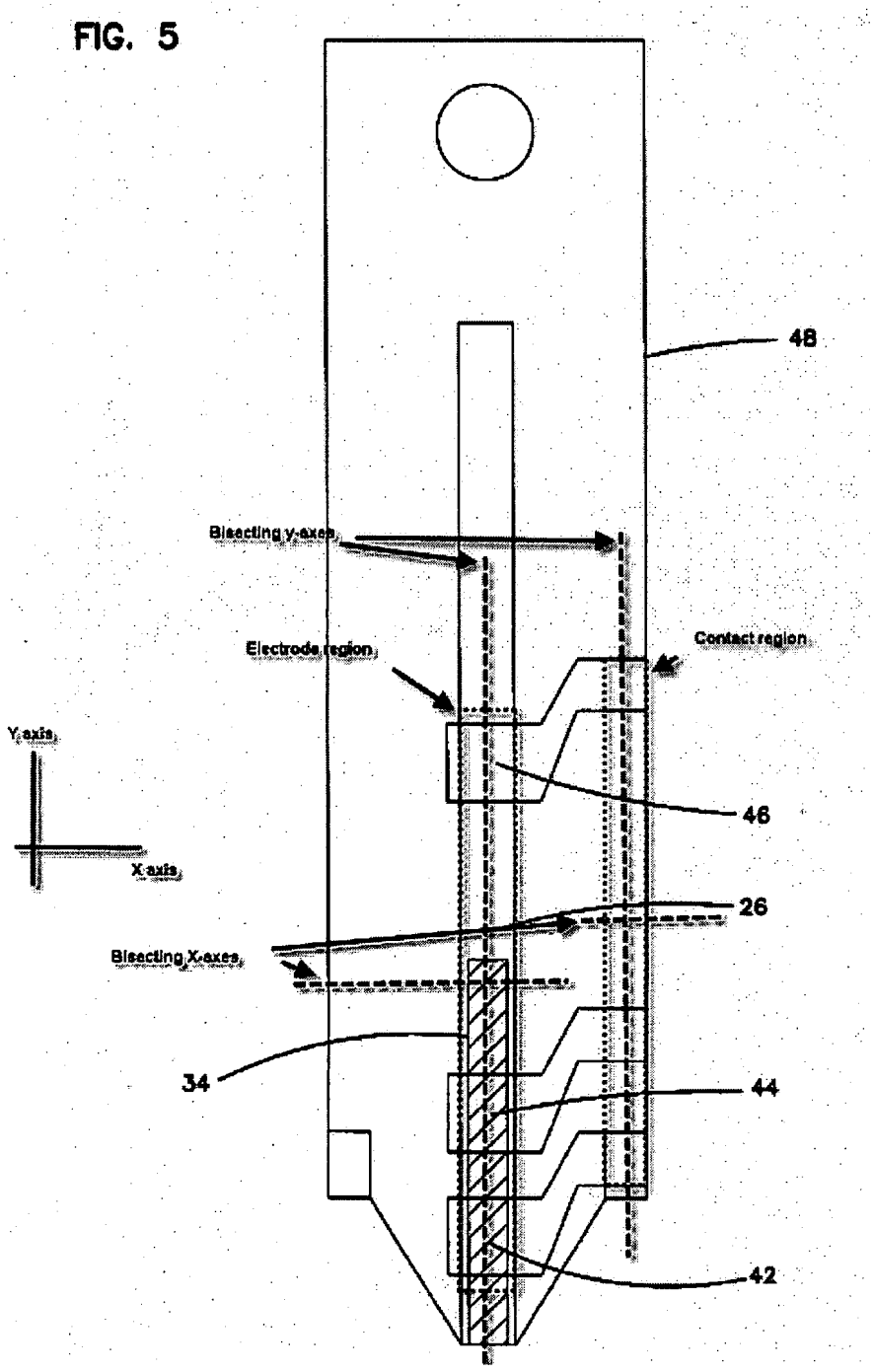
It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a handling tab as taught by Moeller in the invention of Huang because as taught by Moeller, "This assists in withdrawing the strip for [from] its package (6), inserting it into the meter and withdrawing it again after the measurement has been made." See the CAPLUS abstract.

As for the handling tab being textured, this appears to be so from Figure 1 with the triangle and "logo." Even if the triangle and "logo" are not textured, but for example just printed onto the handling tab, it would have been obvious to one with ordinary skill in the art at the time of the invention to texture the triangle and "logo", by for example embossing them onto the handling tab, because this will simplify manufacturing since the triangle and "logo" can be formed onto the handling tab as it is molded by having the mold shaped to also form the triangle and "logo', rather than having to mold the handling tab and then print the triangle and "logo" onto it.

12. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. (WO 98/35225 A1) ("Heller").

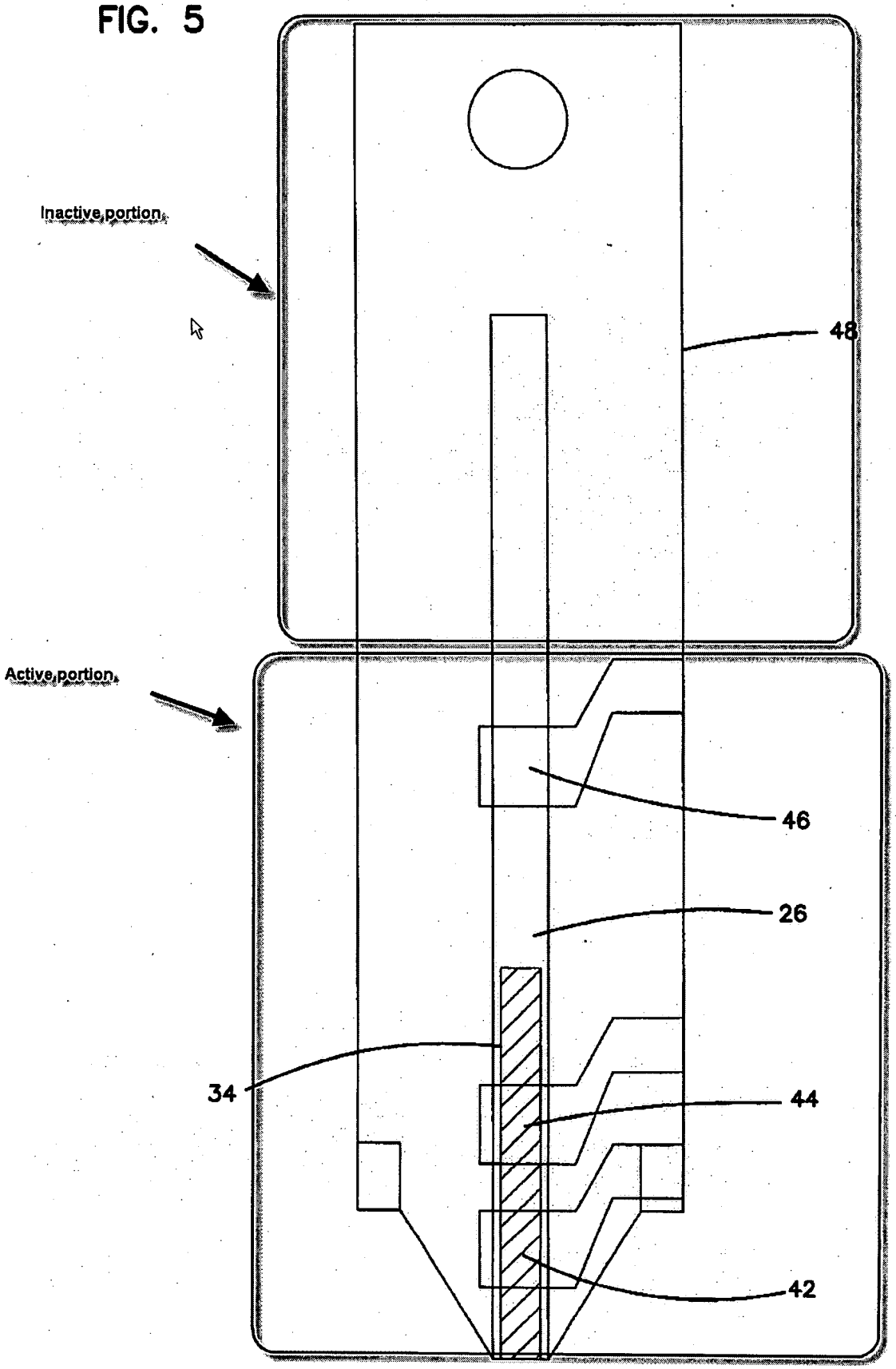
Heller discloses an article comprising an electrochemical sensor strip (abstract) having circuits comprising electrodes in an electrode region connected to contact pads in a contact region by conductive traces wherein the electrode region is off-set from the contact region in both an x direction parallel to the length of the sensor strip and a y direction parallel to the width of the sensor strip. See the labeled reproduction of Figure 5 below.

FIG. 5


48
Bisecting y-axes
Electrode region
Contact region
Y-axis
X-axis
46
26
Bisecting X-axes
34
44
42

Heller further discloses having the circuits located in an active portion and having the article further comprise an inactive portion. See the labeled reproduction of Figure 5 below.

FIG. 5



Heller does not mention a range for the width of the active portion and a range for the length of the active portion. However, barring evidence to the contrary, such as unexpected results, the claimed width and length ranges for the active portion are just a matter of scaling the biosensor for a larger or smaller expected sample volume, especially since Heller discloses that "[t]wo of the three dimensions of the measurement zone, the length and the width, are usually relatively large, between about 1-5 mm." See page 32, lines 23-25.

13. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over McAleer et al. (US 5,708,247) ("McAleer").

McAleer discloses an article comprising an electrochemical sensor strip (abstract) having circuits comprising electrodes in an electrode region connected to contact pads in a contact region by conductive traces wherein the electrode region is off-set from the contact region in both an x direction parallel to the length of the sensor strip and a y direction parallel to the width of the sensor strip. See the labeled reproduction of Figure 1A below.

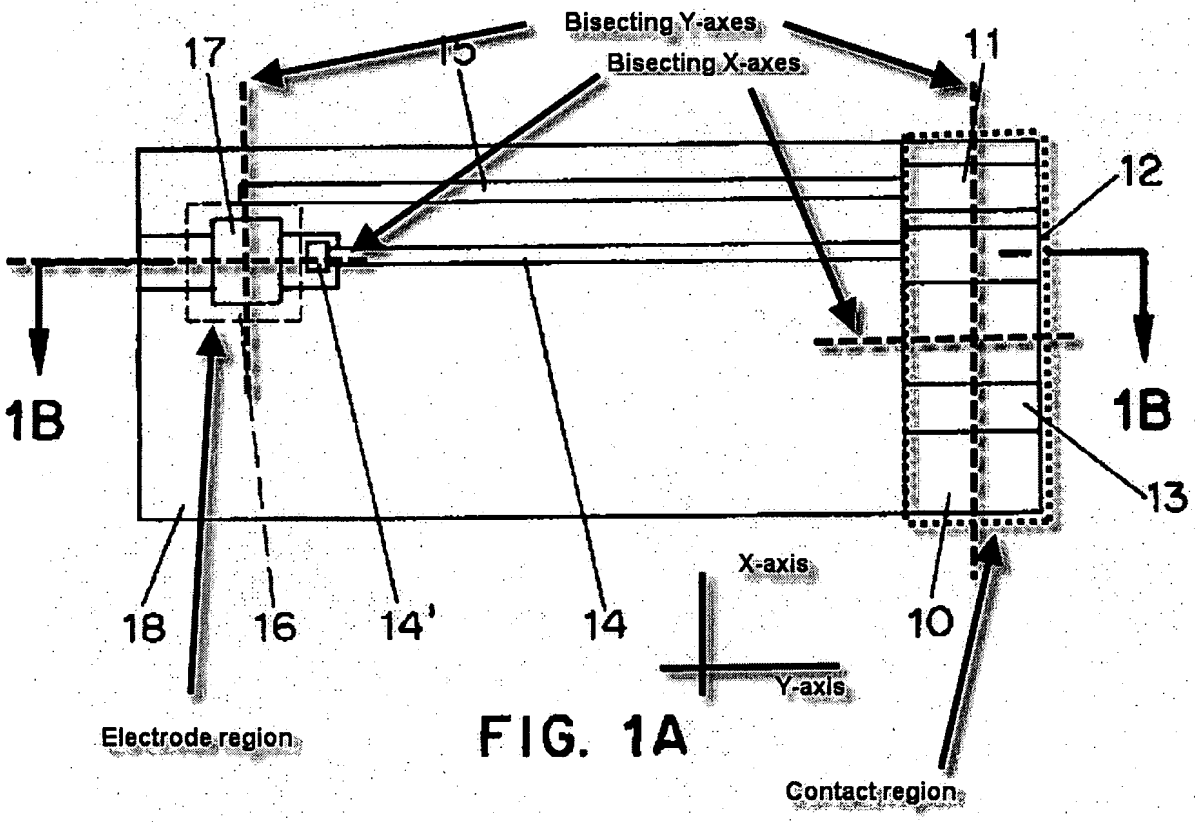


FIG. 1A

McAleer further discloses having the circuits located in an active portion and having the article further comprise an inactive portion. See the labeled reproduction of Figure 1A below.

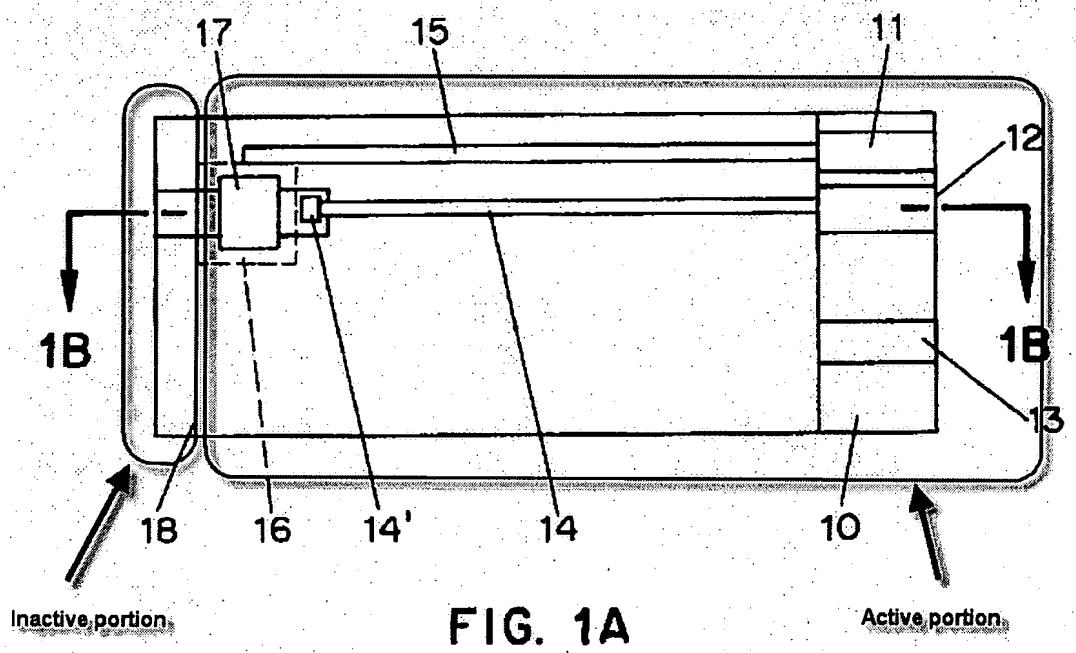


FIG. 1A

McAleer does not mention a range for the width of the active portion and a range for the length of the active portion. However, barring evidence to the contrary, such as unexpected results, the claimed width and length ranges for the active portion are just a matter of scaling the biosensor for a larger or smaller expected sample volume, especially since McAleer discloses a biosensor 5.5 mm wide and 30 mm long. See col. 06:14-17.

14. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huang et al. (US 6,923,894 B2) ("Huang").

Huang discloses an article comprising an electrochemical sensor strip (abstract) having circuits comprising electrodes in an electrode region connected to contact pads in a contact region by conductive traces wherein the electrode region is off-set from the contact region in both an x direction parallel to the length of the sensor strip and a y direction parallel to the width of the sensor strip. See the labeled reproduction of Figure 3 below.

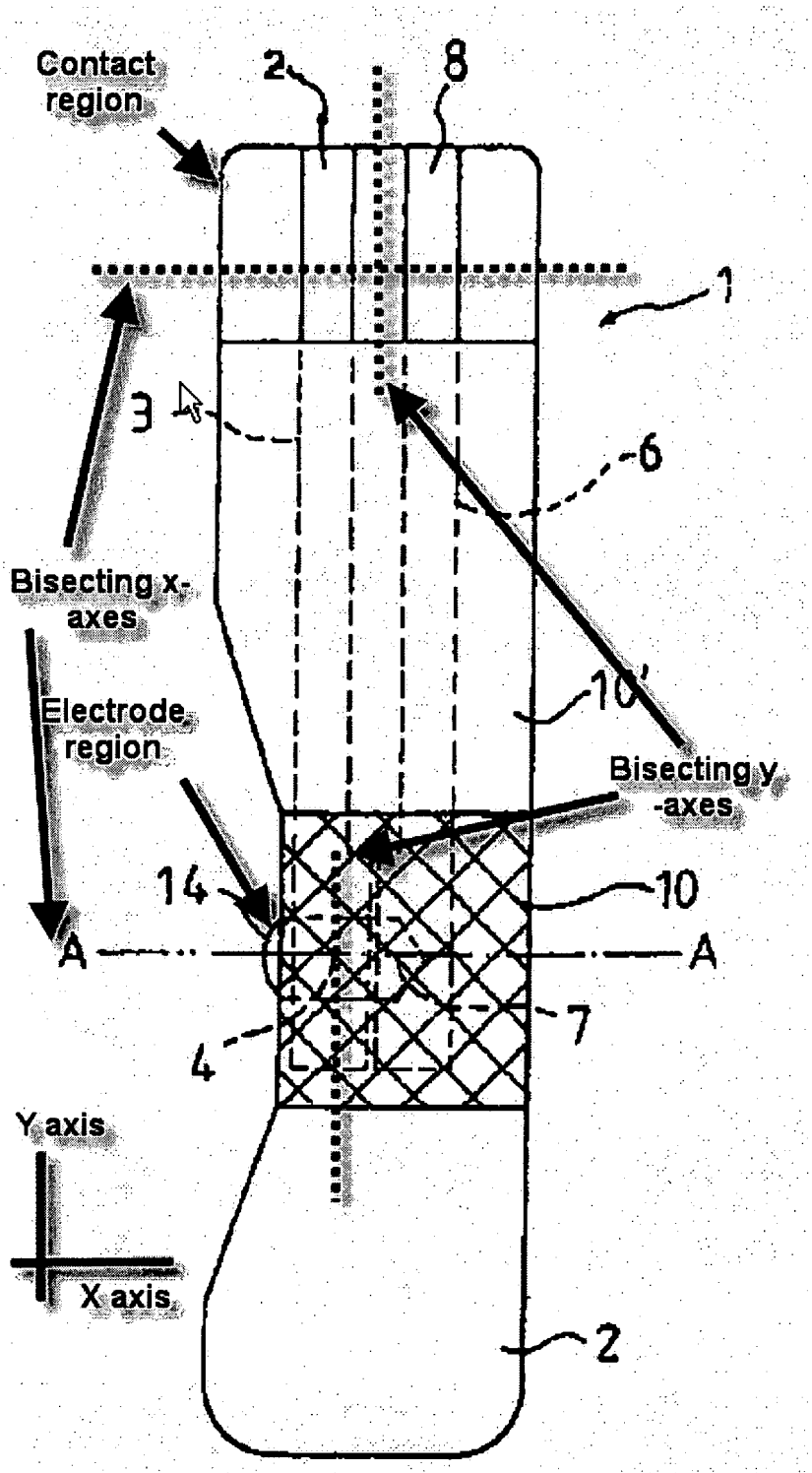

Contact region
2
8
1
3
6
Bisecting x-axes
Electrode region
10'
Bisecting y-axes
14
10
A
A
7
4
Y axis
X axis
2

FIG. 3

Huang further discloses having the circuits located in an active portion and having the article further comprise an inactive portion. See the labeled reproduction of Figure 3 below.

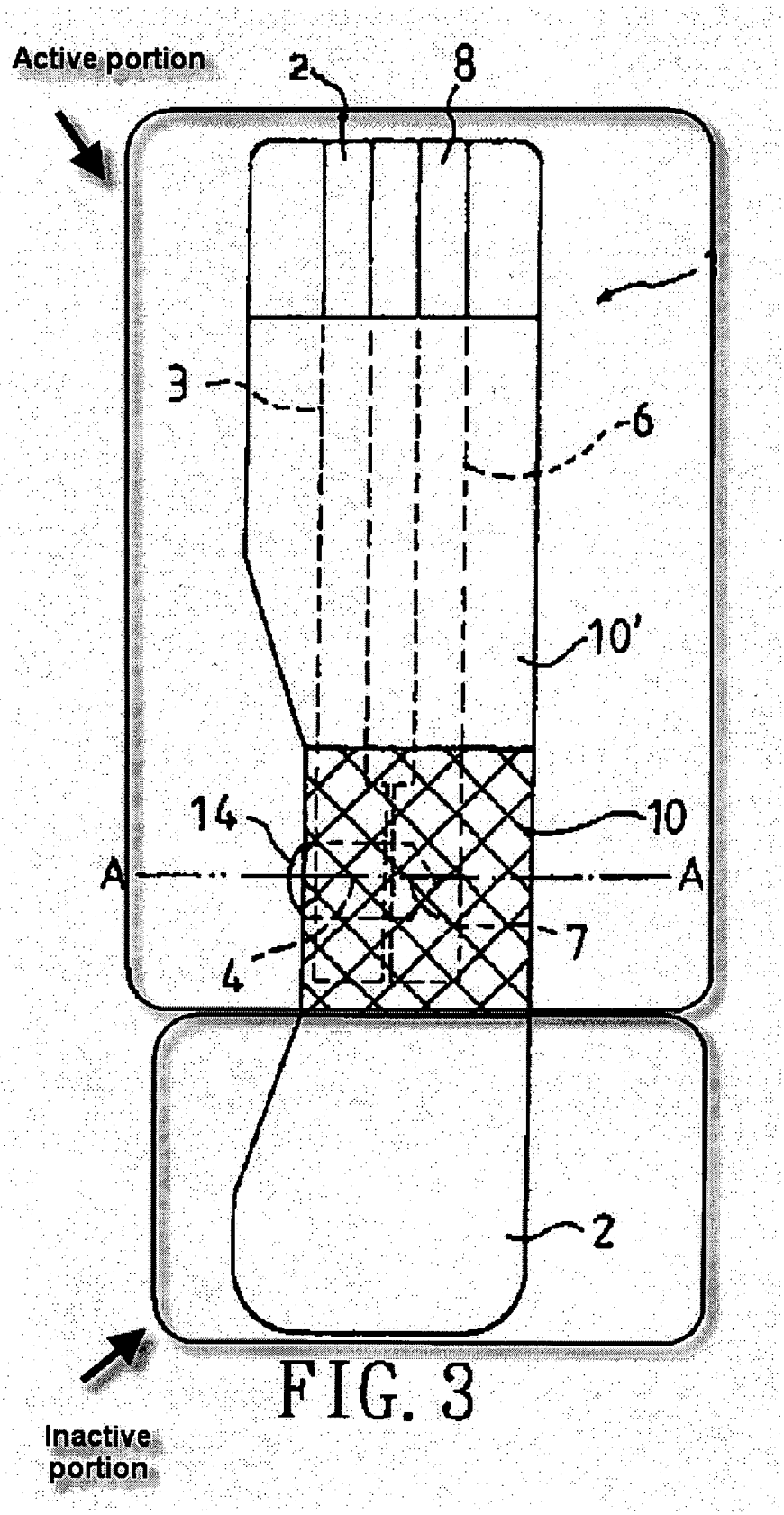


FIG. 3

Huang does not mention a range for the width of the active portion and a range for the length of the active portion. However, barring evidence to the contrary, such as unexpected results, the claimed width and length ranges for the active portion are just a matter of scaling the biosensor for a larger or smaller expected sample volume.

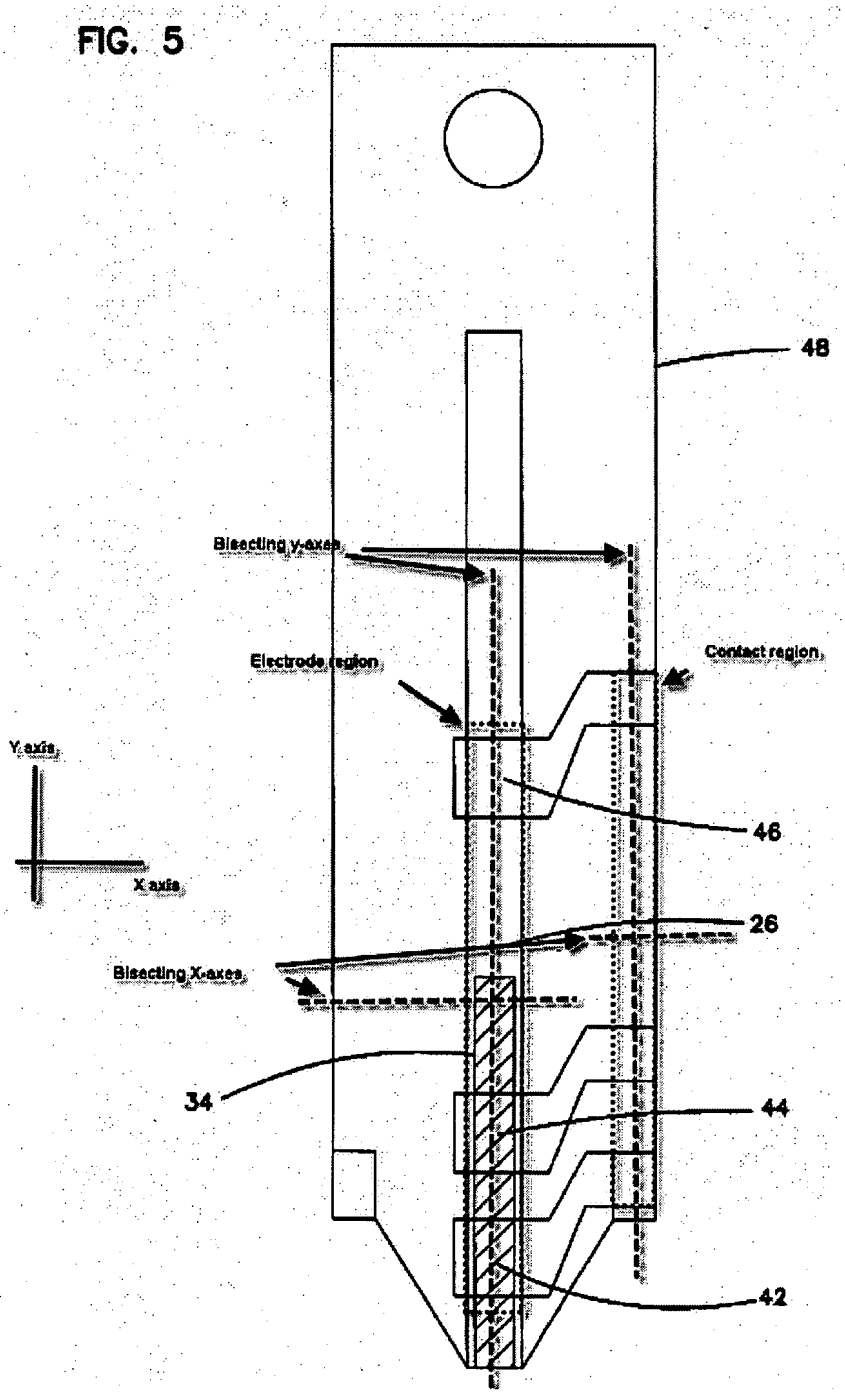
15. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. (WO 98/35225 A1) ("Heller") in view of the JPO English language machine translation of Mariko et al. (JP 2000-019146 A) ("Mariko") and Charlton et al. (US 5,759,364) ("Charlton").

Addressing claim 10, Heller discloses an article comprising an electrochemical sensor strip (abstract) comprising an active portion, the active portion comprising

a substrate (48),

a circuit comprising electrodes in an electrode region connected to contact pads in a contact region by conductive traces wherein the electrode region is off-set from the contact region in both an x direction parallel to the length of the sensor strip and a y direction parallel to the width of the sensor strip. See the labeled reproduction of Figure 5 below,

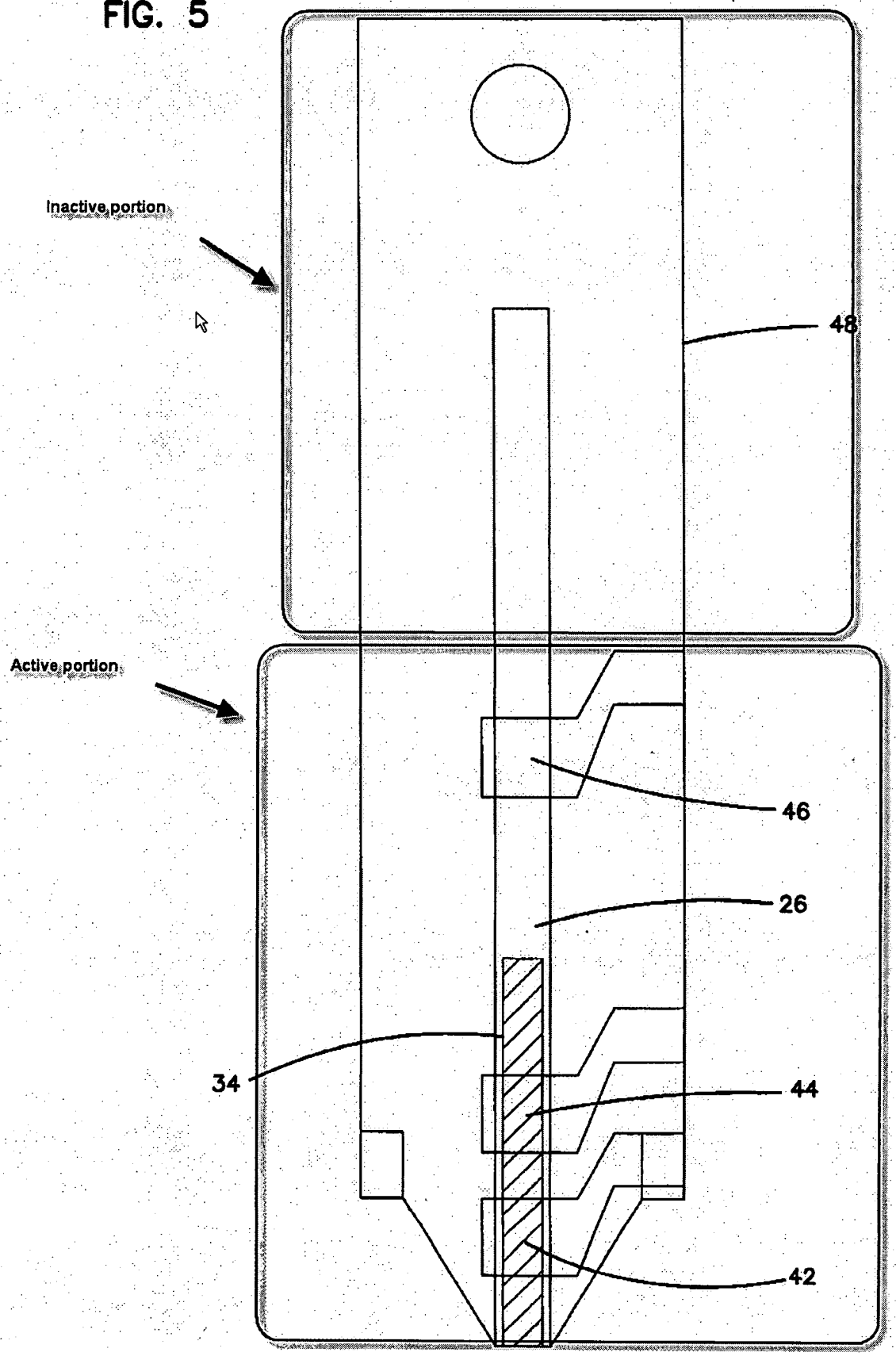
FIG. 5


48
Bisecting y-axes
Electrode region
Contact region
Y axis
X axis
46
26
Bisecting X-axes
34
44
42

and, a polymeric layer (28 or top layer 38 – Figure 3) comprising a channel-forming material over the electrodes.

Heller further discloses having the circuits located in an active portion and having the article further comprise an inactive portion. See the labeled reproduction of Figure 5 below.

FIG. 5



Heller does not mention having the active portion laminated to a portion of a backing material.

Mariko discloses a strip-type electrochemical biosensor having an active portion (1) laminated to a backing material (6). See drawings 1 and 2 and [0011] in the Detailed Description. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a backing material as taught by Mariko in the invention of Heller because then it will be possible to control the temperature of the biosensor to optimize the reaction of the reagent with the sample, especially with a reagent containing enzyme. See [0003] in Detailed Description.

Heller also does not mention providing a hydrophilic layer over the channel-forming material.

Charlton discloses a strip-type electrochemical biosensor comprising a polymeric layer (46) comprising a channel-forming material over the electrodes with a hydrophilic layer over the channel-forming material. See Figure 1; col. 03:10-15; and col. 03:49-53. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a hydrophilic layer as taught by Charlton in the invention of Heller as modified by Mariko because as taught by Charlton this will increase the hydrophilic nature of the capillary space (col. 03:49-53), which will provide at least a slight improvement in sample fill time (col. 11:49-50 and col. 12:24-29).

Addressing claim 11, for the additional limitation of this claim see in Heller page 09:20-27.

16. Claims 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang et al. (US 6,923,894 B2) ("Huang") in view of the JPO English language machine translation of Mariko et al. (JP 2000-019146 A) ("Mariko").

Addressing claim 10, Mariko discloses an article comprising an electrochemical sensor strip (abstract) comprising an active portion, the active portion comprising

a substrate (2),

a circuit comprising electrodes in an electrode region connected to contact pads in a contact region by conductive traces wherein the electrode region is off-set from the contact region in both an x direction parallel to the length of the sensor strip and a y direction parallel to the width of the sensor strip. See the labeled reproduction of Figure 3 below,

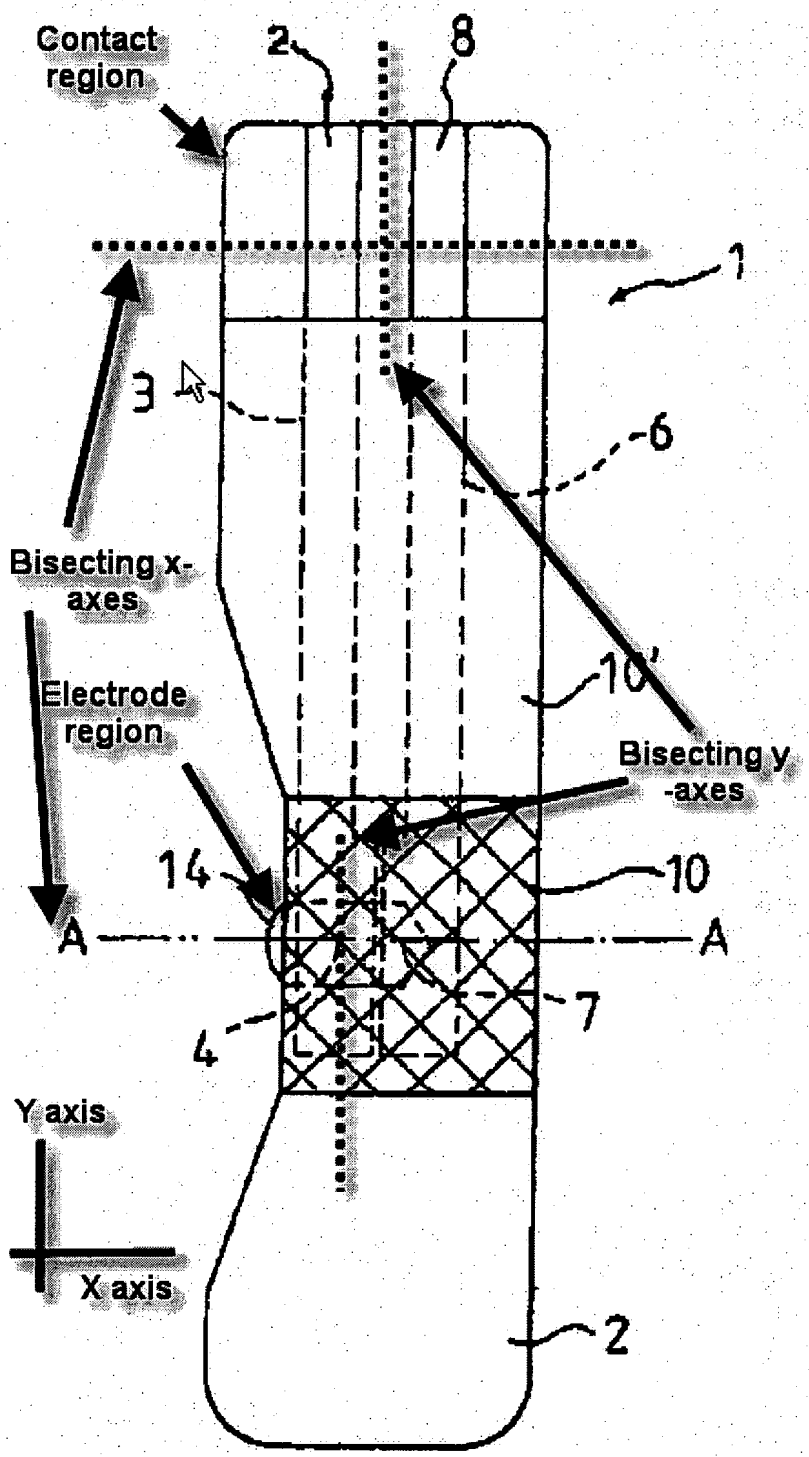

Contact region
2
8
1
3
6
Bisecting x-axes
Electrode region
10'
Bisecting y -axes
14
10
A
A
7
4
Y axis
X axis
2

FIG. 3

Huang further discloses having the circuits located in an active portion and having the article further comprise an inactive portion. See the labeled reproduction of Figure 3 below;

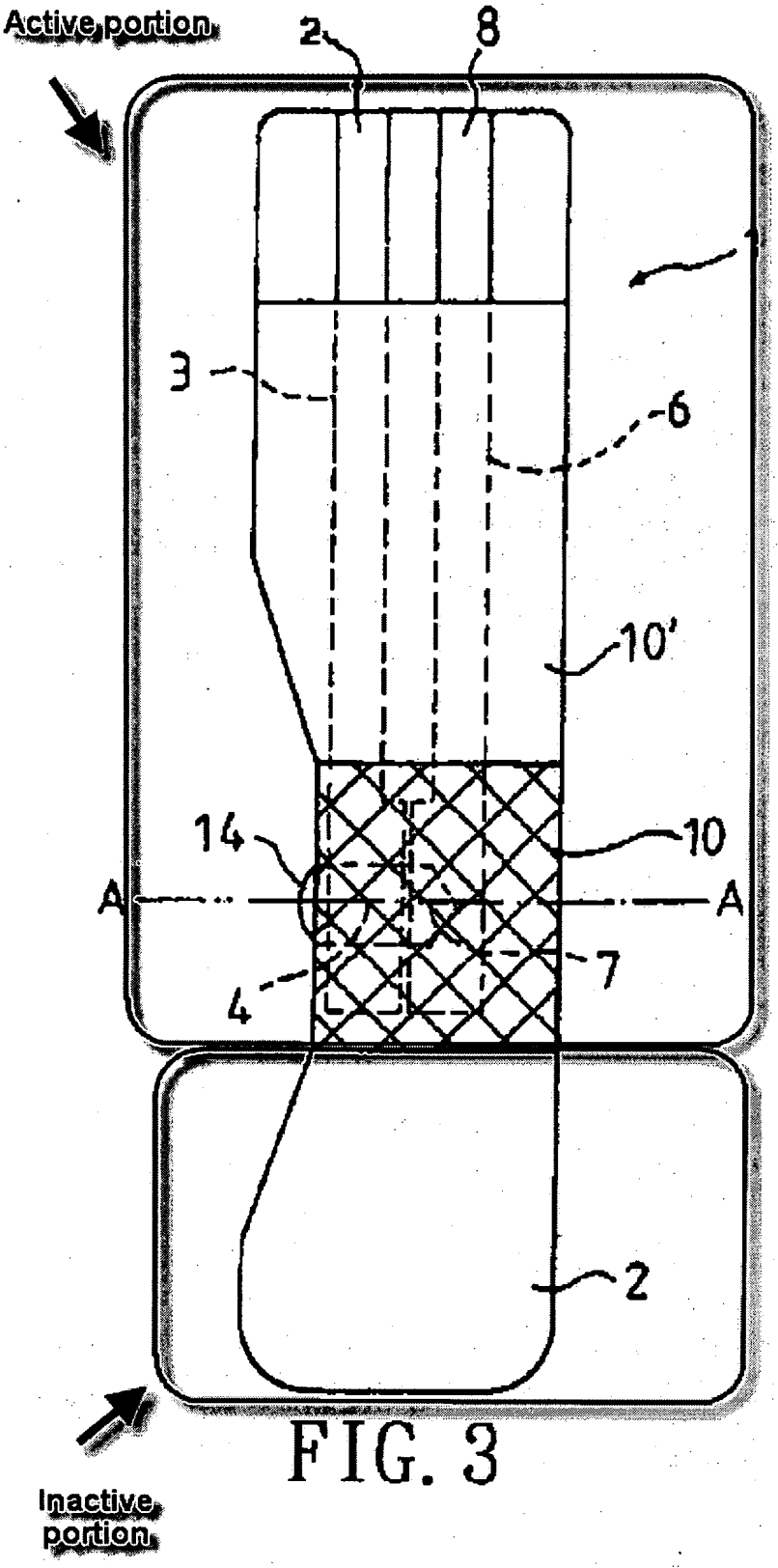


FIG. 3

a polymeric layer (10) comprising a channel-forming material over the electrodes, and a hydrophilic layer (13) over the channel-forming material (col. 06:05-12).

Huang does not mention having the active portion laminated to a portion of a backing material.

Mariko discloses a strip-type electrochemical biosensor having an active portion (1) laminated to a backing material (6). See drawings 1 and 2 and [0011] in the Detailed Description. It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a backing material as taught by Mariko in the invention of Huang because then it will be possible to control the temperature of the biosensor to optimize the reaction of the reagent with the sample, especially with a reagent containing enzyme. See [0003] in Detailed Description.

Addressing claim 11, for the additional limitation of this claim see in Huang col. 04:51-56.

Addressing claim 12, for the additional limitations of this claim see in Huang Figures 3 and 4 and col. 06:05-44.

Addressing claim 13, for the additional limitation of this claim note the semicircular protruding element 14 in Figure 3.

Addressing claims 14 and 15, for the additional limitations of these claims note the alternative embodiments in Figures 7 and 9 in which the fluid sample entrance comprises a sloping portion, at what appears to be 45°, relative to a side edge of the biosensor. Even if not sloping at 45°, but somewhat more or less, barring a contrary showing, having the sloping portion be at 45° is just a matter of optimizing sample introduction and capillary flow to the electrodes. Similarly for having the fluid sample entrance be 1.4 times an entrance that intersects the fluid-wicking channel at an angle of 90°.

Addressing claim 16, for the additional limitation of this claim note that the fluid-wicking channel can be broadly construed to be open to the atmosphere at both ends because it is covered by a porous mesh along its length (col. 06:05-08) and thus open at both ends at least in the top of the end regions.

Addressing claim 17, for the additional limitation of this claim see col. 06:14-17.

17. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huang et al. (US 6,923,894 B2) ("Huang") in view of the JPO English language machine translation of Mariko et al. (JP 2000-019146 A) ("Mariko") as applied to claims 10-17 above, and further in view of Heller et al. (WO 98/35225 A1) ("Heller").

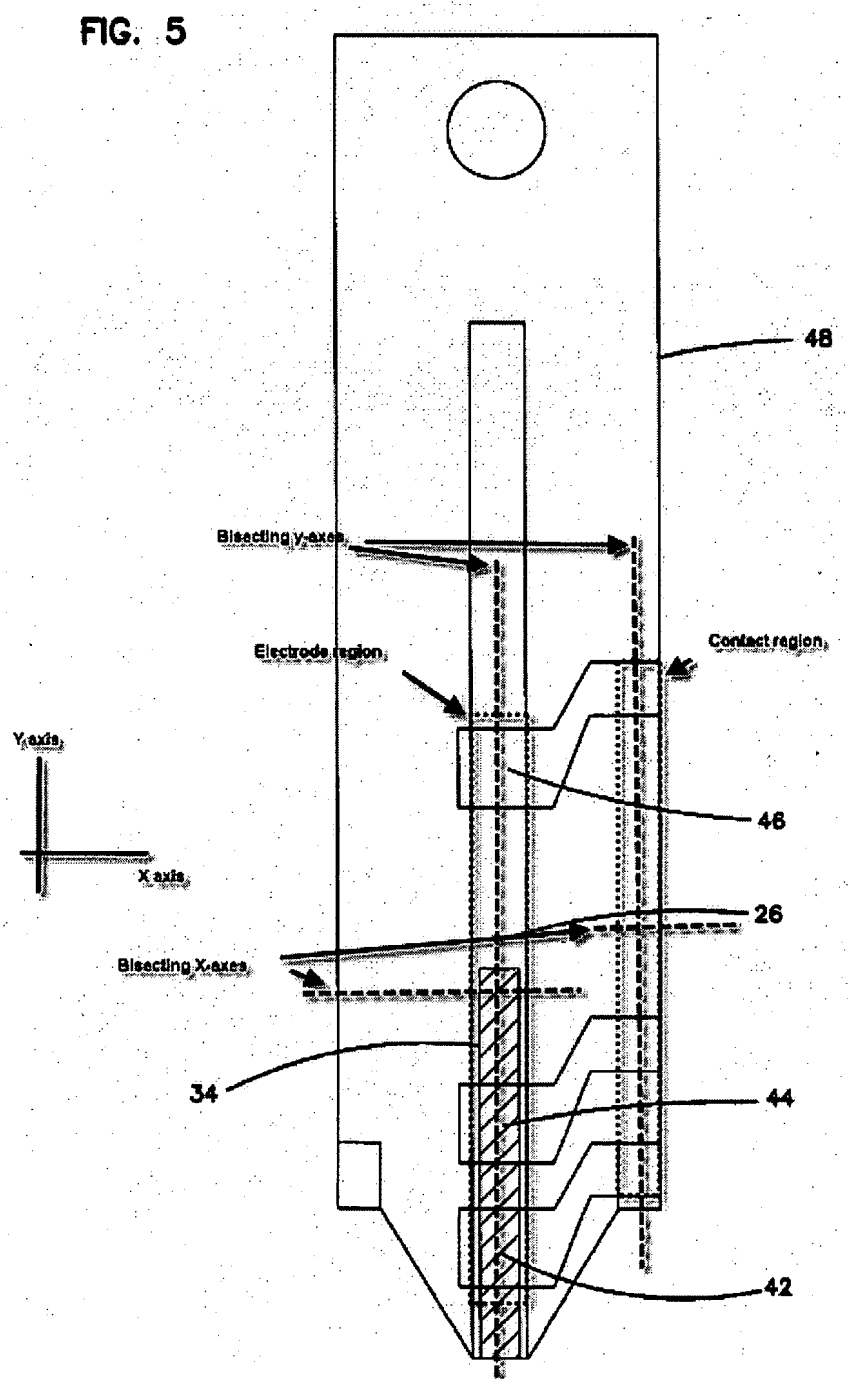
Although Huang as modified by Mariko does not mention whether the fluid – wicking channel has a volume of less than about one microliter, Huang does disclose, "The blood demand for detection is less than 4 μl." See col. 08:30-32.

Heller discloses an electrochemical strip type biosensor with a sample chamber having a volume "... that is preferably less than about 1 μl, more preferably less than about 0.5 μl, and most preferably less than about 0.2 μl." See page 17, lines 01-07. Thus, in light of Heller having the fluid–wicking channel volume be less than about one microliter is just a matter of scaling down the volume of the fluid–wicking channel. This can be achieved, at least in part, by making the channel very narrow, for example by laser etching, or by providing a sorbent in the channel. See in Heller page 20, lines 27-31 and page 21, lines 17-27.

18. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. (WO 98/35225 A1) ("Heller") in view of Ou-Yang et al. (US2003/0204313 A1) ("Ou-Yang").

Heller discloses an article comprising an electrochemical sensor strip (abstract) having circuits comprising electrodes in an electrode region connected to contact pads in a contact region by conductive traces wherein the electrode region is off-set from the contact region in both an x direction parallel to the length of the sensor strip and a y direction parallel to the width of the sensor strip. See the labeled reproduction of Figure 5 below.

FIG. 5


48
Bisecting y-axes
Electrode region
Contact region
Y axis
X axis
46
26
Bisecting X-axes
34
44
42

Heller further discloses that the sensor strip is a blood glucose sensor strip. See page 12, line 28 – page 13, line 01.

Although Heller does not mention also prongs a glucose measuring device having a slot that receives the sensor strip article wherein when the sensor strip is fully inserted into the slot the electrode region of the sensor remains outside of the slot, Heller does disclose that the sensor strip may be paced in a reader. See page 23, lines 19-24.

Ou-Yang discloses that at the time of the invention the conventional glucose measuring device had a slot that receives the sensor strip article wherein when the sensor strip is fully inserted into the slot the electrode region of the sensor remains outside of the slot. See [0015].

It would have been obvious to one with ordinary skill in the art to use the sensor strip of Heller with a conventional glucose measuring device as taught by Ou-Yang because since it is conventional it should be readily available and also because the sensor strip can be easily inserted and removed from the measuring device.

19. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over McAleer et al. (US 5,708,247) ("McAleer") in view of Ou-Yang et al. (US2003/0204313 A1) ("Ou-Yang").

McAleer discloses an article comprising an electrochemical sensor strip (abstract) having circuits comprising electrodes in a region connected to contact pads in a contact region by conductive traces wherein the electrode region is off-set from the contact region in both an x direction parallel to the length of the sensor strip and a y direction parallel to the width of the sensor strip. See the labeled reproduction of Figure 1A below.

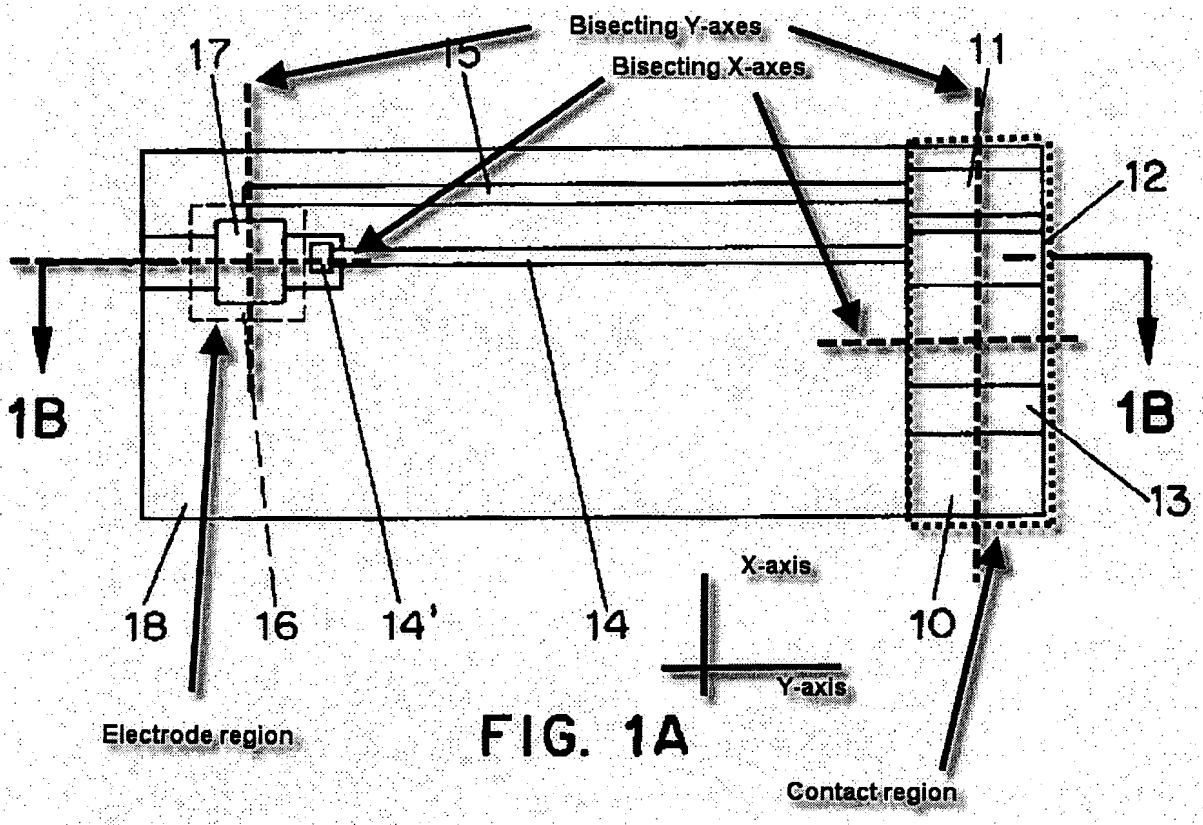


FIG. 1A

McAleer further discloses that the sensor strip is a blood glucose sensor strip. See col. 03:39-42.

Although McAleer does not mention also prongs a glucose measuring device having a slot that receives the sensor strip article wherein when the sensor strip is fully inserted into the slot the electrode region of the sensor remains outside of the slot, McAleer does disclose that the sensor strip may be paced in a reader. See col. 03:49-51.

Ou-Yang discloses that at the time of the invention the conventional glucose measuring device had a slot that receives the sensor strip article wherein when the sensor strip is fully inserted into the slot the electrode region of the sensor remains outside of the slot. See [0015].

It would have been obvious to one with ordinary skill in the art to use the sensor strip of McAleer with a conventional glucose measuring device as taught by Ou-Yang because since it is conventional it should be readily available and also because the sensor strip can be easily inserted and removed from the measuring device.

20. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huang et al. (US 6,923,894 B2) ("Huang") in view of Ou-Yang et al. (US2003/0204313 A1) ("Ou-Yang").

Huang discloses an article comprising an electrochemical sensor strip (abstract)

having circuits comprising electrodes in a region connected to contact pads in a contact region by conductive traces wherein the electrode region is off-set from the contact region in both an x direction parallel to the length of the sensor strip and a y direction parallel to the width of the sensor strip. See the labeled reproduction of Figure 3 below.

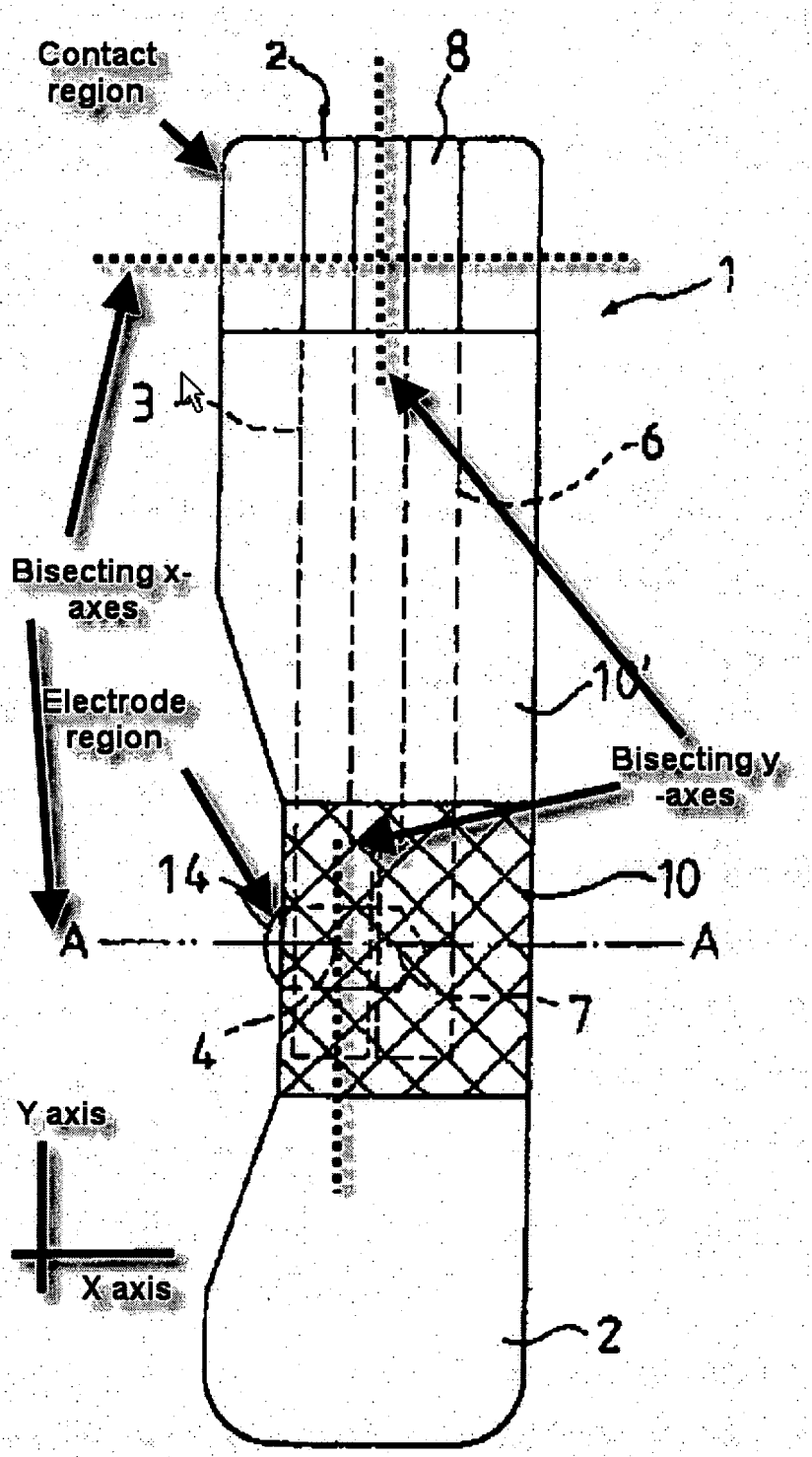

Contact region
2
8
1
3
6
Bisecting x-axes
Electrode region
10'
Bisecting y-axes
14
10
A
A
7
4
Y axis
X axis
2

FIG. 3

Huang further discloses that the sensor strip is a blood glucose sensor strip. See col. 05:05-28.

Although Huang does not mention also prongs a glucose measuring device having a slot that receives the sensor strip article wherein when the sensor strip is fully inserted into the slot the electrode region of the sensor remains outside of the slot, Huang does disclose that the sensor strip may be paced in a reader. See col. 05:05-28.

Ou-Yang discloses that at the time of the invention the conventional glucose measuring device had a slot that receives the sensor strip article wherein when the sensor strip is fully inserted into the slot the electrode region of the sensor remains outside of the slot. See [0015].

It would have been obvious to one with ordinary skill in the art to use the sensor strip of Huang with a conventional glucose measuring device as taught by Ou-Yang because since it is conventional it should be readily available and also because the sensor strip can be easily inserted and removed from the measuring device.

Allowable Subject Matter

21. Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

22. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 4: the combination of limitations requires the electrode region and contact region to be "off-set such that they form an L shape, the interior of which shape forms an edge of the sensor strip and wherein the electrode region protrudes beyond the contact region in the x region." As stated by Applicant,

> An advantage of the L shaped circuit is that the fluid wicking channel does not extend the entire width of the circuit portion. This results in a reduced fluid sample volume requirement, which allows for the use of a smaller circuit. The L-shaped circuits thus minimizes the size of circuit needed in the test strip. A sensor strip built for ease of handling would be wide, but if the fluid wicking channel extends the width of the strip a larger fluid sample would be required. The L-shape allows a shorter wicking channel, even with a wide sensor strip. As illustrated in Fig. 7, the L-shaped circuit allows for a small electrode area, while still providing a large contact area. This is desirable because the contact portion interfaces with an analyte measuring device and the contact pads need to be large enough to establish a good connection with the conductive features of the measuring device. In addition, the L-shaped circuit achieves the small electrode area and large contact area with short trace elements. This keeps the active portion of the sensor small and cuts down on the use of expensive materials required for the active portion.

> The L-shaped circuit also prevents contaminating the analyte measuring device when the sensor circuit is inserted to obtain a reading because the electrode area, which receives the fluid sample, is physically separated from the contact area, which is inserted into the measuring deice, thereby eliminating or minimizing the likelihood of the analyte sample entering the measuring device. *See page 10, line 22 – page 11, line 09 of the specification.*

In the embodiment of Figure 5 of Heller and of Figure 3 of Huang the electrode region and the contact region are parallel.

In the embodiment of Figure 1A of McAleer the electrode region is located at the front end of the biosensor and is separated from the contact region, which is located at the back end of the biosensor, by a substantial portion of the length of the biosensor.

Specification

23. The disclosure is objected to because of the following informalities:

a) on page 5 the serial number of the referenced copending application is missing.

b) page 7, line 09 refers to a "line 450" that is not shown in Figures 41-4e.

c) page 11, line 12 refers to non-existent Figure 3d.

Appropriate correction is required.

International Search Report for International Application No. PCT/US2004/033948 ("Search Report")

24. US 5741634 A (Nozoe et al.) is cited as an "X" reference against claims 1-3, 5, 10, 11, 19, and 20 in the Search Report. It has been applied above in rejections under 35 U.S.C. 102 (b).

25. US 6,175752 B1 (Say et al.) and DE 10020445 A1 (Schlagheck Design GMBH) have been applied as "Y" references, apparently in combination, against claims 1, 5, 6, 8-11, 19, and 20. However, this is not a proper combination of references for meeting the claim limitations of claims 5, 6, 8-11, and 20. US 6,175752 B1 is directed to an in vivo sensor, that is, a sensor that is to be implanted in a patient (col. 01:01-11 and col. 02:62-63). DE 10020445 A1, on the other hand, is directed to an in vitro sensor. So the handling tab disclosed by DE 10020445 A1 would not be used with the sensor of US 6,175752 B1 since the sensor is to be implanted in a patient. To provide the handling tab of DE 10020445 A1 with the sensor of Figure 2 of US 6,175752 B1 would unnecessarily make the sensor lager than necessary when a small sensor is clearly more desirable (Say et al. - col. 01:60-63). Also, since the sensor of US 6,175752 B1 is to be implanted in a patient it would not be used with a glucose measuring device as required by claim 20. US 6,175752 B1 has been used above to reject claims 1 and 19 under 35 U.S.C. 102 (b).

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Nogueroła
Primary Examiner
AU 1753
May 12, 2007

Continuation of Attachment(s) 6). Other: IDS of 02/28/2005; IDS of 02/25/2005; and IDS of 02/11/2005 .